higher incomes over children in families with lower incomes. If the State does not want to administer two caps, it does have the option to place the 2.5 percent cap or a flat amount equal to 2.5 percent of the family's income on the entire enrollee population that is subject to cost sharing. This should have a minimal impact on the amount of cost sharing States will impose; particularly in light of the George Washington University study, as indicated by the commenter, which found that it is rare for families to reach the 5 percent cap at all. The State may also choose to impose premiums instead of copayments, coinsurance or deductibles, so that tracking of cost sharing is not necessary.

Comment: One commenter noted that the separate calculation requirement applied to each beneficiary's family to ensure that the five percent cost-sharing limitation is met is unwieldy and expensive. In this commenter's view, it is unlikely that opportunities for participation in premium assistance programs will be aggressively pursued. The commenter also asserted that our policy eliminates the opportunity for children in SCHIP to be enrolled in premium assistance programs.

Response: For targeted-low income children in families with income greater than 150 percent of the FPL, section 2103(e)(3)(B) requires States to ensure that cost sharing does not exceed 5 percent of a family's income. The statute does not exempt States from this cap if they provide child health assistance through an employer-sponsored insurance program. Therefore, we have not included any exceptions to the rules for States utilizing premium assistance programs.

Comment: One commenter stated that the regulation goes beyond legislative intent by requiring that copayments and deductibles be included in the computation of the maximum cost sharing for a family with income above 150 percent of the FPL. In support of this point, the commenter noted that section 2103(e)(3)(B) of the Social Security Act limits ''enrollment fees, premiums, or similar charges'' to five percent of the family's income. The commenter asserted that deductibles and copayments are not ''similar charges,'' because they are not prepayments for benefits coverage; rather, they are payments made to treating providers at the time of service delivery. By requiring States to include deductibles and copayments in the calculation of the maximum, HCFA has created major administrative problems, especially for the majority of states that are using HMOs or other insurers in this commenter's view. The commenter recommended that we limit the calculation of the maximum amount to ''enrollment fees, premiums and similar charges''. The State merely has to make sure it sets a premium below the maximum of 5 percent of family income.

Response: Section 2103(e)(3)(B) of the Act provides that ''any premiums, deductibles, cost sharing, or similar charges imposed under the State child health plan may be imposed on a sliding scale related to income, except that the total annual aggregate cost sharing with respect to all targeted low-income children in a family under this title may not exceed five percent of such family's income for the year involved.'' The statute's reference to ''deductibles, cost sharing, and similar fees'' clearly indicates that the charges to be counted towards the cumulative cost-sharing maximum are not to be limited to premiums and enrollment fees. However, States have the option to impose only premiums under their SCHIP plans.

Comment: One commenter noted an error in this section. Specifically, the commenter pointed out that the proposed regulation text states that total cost sharing imposed on families with incomes above 150 percent of the FPL not exceed the maximum permitted under § 457.555(c). It should be § 457.560(c).

Response: The commenter is correct that the reference should have been to § 457.560(c). In addition, in order to eliminate this confusion and redundancy in the final regulation text, we have eliminated section § 457.545 and reflected the policy at § 457.560(c).

14. Grievances and Appeals (§ 457.565)

We proposed that the State must provide enrollees in a separate child health plan the right to file grievances and appeals in accordance with proposed § 457.985 for disenrollment from the program due to failure to pay cost sharing. We address comments on proposed § 457.565 in subpart K, Enrollee Protections, which now contains the provisions relating to applicant and enrollee protections. We have deleted proposed § 457.565 in an effort to consolidate all provisions relating to the review process in the new subpart K.

15. Disenrollment Protections (§ 457.570)

Section 2101(a) of the Act provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children. Based upon this provision of the statute, we proposed in § 457.570 to require that States establish a process that gives enrollees reasonable notice of, and an opportunity to pay, past due cost-sharing amounts (premiums, copayments, coinsurance, deductibles and similar fees) prior to disenrollment. We requested comments on this requirement, including specific comments on the determination of an amount of time that would give enrollees reasonable notice and opportunity to pay cost-sharing amounts prior to disenrollment. We stated that we would request that States with approved plans submit this additional information after publication of the proposed rule and prior to the State's onsite review. We stated that we would also ask the State to include a description of its process in future amendments to its State plan.

Comment: One commenter noted that disenrollment occurs in the Hispanic population because the SCHIP process is extremely paper-intensive. In this commenter's view, one of the most common reasons for disenrollment from SCHIP is the termination of benefits due to the failure to provide premium payments in a timely manner. They stated that, Hispanics in eligible income brackets, in particular, tend to deal in a cash economy, making it difficult to pay SCHIP premiums in the preferred method of payment. In order to slow disenrollment the commenter stated that it is necessary to devise a plan to eliminate the barrier to payment, and effectively reduce the rate of disenrollment among Hispanics.

Response: The SCHIP statute specifically allows States to impose premiums on the SCHIP population within statutorily defined limits. However, we encourage States to be flexible in the methods of payment permitted for cost-sharing charges and to allow grace periods and to provide adequate notice when payments are not made. We have clarified in the final rule that the State plan must describe the disenrollment protections provided to enrollees. In addition, States might monitor disenrollments by reason for disenrollment and determine whether certain groups of enrollees are more likely than others to lose coverage due to failure to meet the cost-sharing requirements. In addition, we encourage States to work with advocates from the Hispanic community to devise culturally sensitive methods to inform consumers about cost sharing and

devise appropriate procedures for obtaining necessary premium payments.

Comment: One commenter noted that the appeals procedures should not be structured in such a way as to give a child's family an incentive to drop SCHIP coverage for a child until he or she needs health services. This practice undermines basic insurance principles and threatens the financial integrity of SCHIP programs because it would result in the pool of enrollees being significantly more sick and more costly than would otherwise be anticipated, in this commenter's view. They stated that the result of such a practice would be to unnecessarily increase the costs of providing coverage to enrollees, which in turn would potentially threaten the viability of the State's SCHIP. The commenter recommended that HCFA revise the regulation to require States to address this issue when they define the circumstances under which a member will be permitted to re-enroll following voluntary disenrollment or disenrollment for nonpayment of premiums or cost sharing.

Response: We are aware that there may be problems when an enrollee is disenrolled and permitted to re-enroll. Some States have adopted lock-out periods to promote the appropriate utilization of health insurance, although other States have discontinued their lock-out periods because they did not find any significant increase in sicker enrollees. States have the flexibility to design their programs based on their unique circumstances to assure that eligible enrollees maintain coverage.

Comment: Many commenters agreed that enrollees should be given an opportunity to pay past due cost sharing prior to disenrollment. Many commenters noted that there should not be any lock-out periods, that States should give families every opportunity to pay past due premiums and at a minimum, grant grace periods of 60 days for the non-payment of premiums. One commenter suggested that the preamble urge States to conduct a Medicaid screen if a child's family is unable to pay premiums due to financial hardship.

Response: We agree that, at the very least, a State should give enrollees a chance to pay past due cost sharing prior to disenrollment. While many commenters noted that lock-out periods should not apply, it is appropriate to allow States to implement a lock-out period so that individuals are not obtaining or maintaining SCHIP coverage only when they need services. We also agree with the comment encouraging States to perform a Medicaid eligibility screen for enrollees who are unable to pay cost-sharing charges due to financial hardship and have emphasized this elsewhere in comments to this final rule. We have added that the disenrollment process must afford enrollees the opportunity to show that their family income has declined prior to being disenrolled for nonpayment of cost-sharing charges. In the event that such a showing indicates that the enrollee may have become eligible for Medicaid or a lower level of cost sharing under separate child health plans, States should take action to either enroll the child in Medicaid or adjust the child's cost sharing category. We expect this new protection will afford enrollees the opportunity to enroll in Medicaid if they have become eligible.

Comment: A few commenters noted specific standards regarding disenrollment protections that HCFA should articulate in the final regulation. Specifically, the commenter recommended that HCFA clearly define what constitutes reasonable notice; clarify that only the State may disenroll a child or impose any other sanction due to an enrollees's failure to pay cost sharing; provide that disenrollment can only be effected after all reasonable steps have been undertaken to avoid disenrollment; require that families should be offered the opportunity to establish a repayment plan; and that families cannot be subjected to penalties or interest for past due payments.

Response: The regulation at § 457.570 regarding disenrollment protections provides enrollees with meaningful protections in connection with any disenrollment related to cost sharing while giving the States flexibility to establish processes consistent with the goals and structure of their programs. We do not accept the commenter's recommendation that HCFA be prescriptive in the regulation regarding disenrollment protections, because each State's SCHIP program is separate and distinct and should retain flexibility accordingly.

Comment: One commenter noted that States should be given the flexibility to decide how they will implement this standard. Specifically, this commenter believes it is administratively burdensome to track a specific grace period before a family is disenrolled from SCHIP.

Response: States are granted flexibility to establish disenrollment procedures under § 457.570 of the final rule. These procedures must be included as part of the State plan. However, the rule does require States to provide reasonable notice prior to disenrollment and provides for a period of time (grace period) for the enrollee's family to pay past due amounts. The rule also enables the State to evaluate the enrollee's financial situation prior to disenrollment to ensure he or she does not qualify for Medicaid.

Comment: One commenter complained that the proposed disenrollment protections were too burdensome because they do not permit disenrollment for nonpayment of premiums even after reminder notices have been sent. One commenter noted that implementing a grace period before disenrollment will result in duplicative coverage and wasted funding since research shows that the primary reason a family fails to pay its monthly premium is that the family has obtained other coverage.

Response: The regulation at § 457.570 regarding disenrollment protections gives the States flexibility to establish processes consistent with the goals and structures of their programs. A disenrollment process without any grace period could result in a system that would disenroll a family prematurely (without adequate notice) and interrupt the family's continuity of care. Therefore, we continue to require that States establish a process that gives enrollees reasonable notice of, and an opportunity to pay past due premiums, copayments, coinsurance, deductibles, or similar fees prior to disenrollment.

Comment: One commenter noted that there may be cases in which the individual responsible for paying a premium is not the custodial party or head of household for the children. In such cases, the commenter stated that notices of disenrollment for failure to pay a premium need to be provided to both the payer of the premiums and the SCHIP beneficiary. Also, if premiums are owed by an individual other than the head of household, and are not paid, the family receiving the SCHIP benefits should not be subject to penalties, and should be given an opportunity to assume responsibility for making future payments.

Response: We agree with the commenter and recommend that States review all viable financial options of an enrollee prior to disenrolling an enrollee due to a parent or caretaker's failure to pay cost sharing. We will also require that States include a disenrollment policy as part of its public schedule, so that all family members who are responsible for paying cost sharing on behalf of the enrollee are informed of the disenrollment process.

F. Subpart G—Strategic Planning, Reporting, and Evaluation

1. Basis, Scope, and Applicability (§ 457.700)

As proposed, this subpart sets forth the State plan requirements for strategic planning, monitoring, reporting, and evaluation under title XXI. Specifically, this subpart implements sections 2107(a), (b), and (d) of the Act, which relate to strategic planning, reports, and program budgets; and section 2108 of the Act, which sets forth provisions regarding annual reports and evaluations.

In the preamble to the proposed rule, we noted the importance of reporting and evaluating SCHIP data. We stated that these activities will provide the critical information necessary for meeting Federal reporting requirements, documenting program achievements, improving program function, and assessing program effectiveness in achieving policy goals. We also described that our information dissemination policy will include making State annual reports, State evaluations and a summary of State expenditures and statistical reports regularly available on the Internet.

Comment: Several commenters strongly supported the statement in the preamble to proposed § 457.700 indicating that we plan to make annual reports, State evaluations, and summaries of State reports regularly available for public access on the Internet. One commenter recommended that an annual, separate, consumer-friendly SCHIP State-by-State status report be available in written and electronic form to the public.

Response: We plan to continue the information dissemination policy that includes making annual reports, State evaluations, and a summary of State expenditures and statistical reports regularly available on the Internet, to the maximum extent possible. We have already produced two State-by-State reports on SCHIP enrollment and released a summary of the States' March 31, 2000 evaluations. We plan to produce and make available future informational reports based on State evaluations, enrollment data, and other sources. We encourage the public not only to access our web site to read the State annual reports and other State-specific information but also to access individual State web sites. In addition, we note that several national organizations, such as the National Governors' Association (NGA), the National Academy for State Health Policy (NASHP), the Children's Defense Fund, the National Conference of State Legislators (NCSL), the American Public Human Services Association (APHSA), the American Academy of Pediatrics (AAP), and other organizations representing State and local governmental entities periodically produce State-by-State SCHIP status or informational reports that are available to the public. We encourage the public to utilize these resources.

Comment: Several commenters stated that we should require States to collect information in a manner that does not discourage individuals from applying for SCHIP. Techniques suggested for achieving this goal include: explaining to participants the purpose of the information collected, assuring confidentiality of information collected, and disclosing that the failure to provide the requested information will not be used to deny eligibility.

Response: We agree with commenters on the importance of gathering evaluative information without creating barriers to participation in SCHIP; and we know this is a concern for States and other stakeholders who have worked to simplify and streamline the application process. We also recognize the flexibility given to States in creating and evaluating their uniquely designed SCHIP programs. We encourage States to be mindful of potential barriers created by collecting information and to create systems that do not prevent potential enrollees from applying for health insurance coverage under SCHIP.

In addition, as noted later in the responses to comments on §§ 457.740 and 457.750, in conjunction with the requirement that States collect and report information about the gender, race, ethnicity and primary language of SCHIP enrollees; we emphasize the importance of States ensuring through the application process that failure to provide information on one of these areas will not affect a child's eligibility for the program. In addition, States must request this information in a manner that is linguistically and culturally appropriate so as not to discourage enrollment in the program.

2. State Plan Requirements: Strategic Objectives and Performance Goals (§ 457.710)

In accordance with section 2107(a) of the Act and the Government Performance and Results Act of 1993 (GPRA), proposed § 457.710 encouraged program evaluation and accountability by requiring the States to include in their State plan descriptions of the strategic objectives, performance goals, and performance measures the State has established for providing child health assistance to targeted low-income children under the plan and for otherwise maximizing health benefits coverage for other low-income children and children generally in the State.

In accordance with section 2107(a)(2) of the Act, we proposed at § 457.710(b) that the State plan must identify specific strategic objectives related to increasing the extent of health coverage among targeted low-income children and other low-income children. We encouraged States to view the development of strategic objectives as a process that involves translating the basic overall aims of the State plan into a commitment to achieving specific performance goals or targets, recognizing that there will be variation among States in specific evaluation approaches and terminology. One of the strategic objectives established in the Act is the reduction in the number of low-income, uninsured children.

Under section 2107(a)(3) of the Act, States must identify one or more performance goals for each strategic objective. We proposed to implement this statutory provision at § 457.710(c). We noted in the preamble that detailed performance goals should facilitate the State's ability to assess the extent to which its strategic objectives are being achieved. In addition, we provided guidance on factors States should consider in drafting strategic objectives and performance goals, noting that they should consider not only the general population targeted for SCHIP enrollment, but special population subgroups of particular interest as well.

In accordance with section 2107(a)(4) of the Act, proposed § 457.710(d) provides that the State plan must describe how performance under the plan will be measured through objective, independently verifiable means and compared against performance goals. We set forth specific examples of acceptable performance measures in the preamble to the proposed rule.

Comment: We received several comments suggesting that we require States to report on a common core of widely-used, objective, standardized, and child-related performance measures and strategic objectives designated by the Secretary. Furthermore, commenters recommended that we require the results of these standard performance measures to be included in the States' annual reports. Some commenters feared that, absent a requirement to report a common set of measures, the information collected might be meaningless and could not be used to evaluate or compare the effectiveness of State plans.

Commenters recommended strategic objectives including: the need to reduce and/or eliminate racial and ethnic disparities in children's health insurance coverage; the need to reduce and/or eliminate barriers to health coverage for children with disabilities; the need to reduce stigma and barriers to access in Medicaid; the need to ensure that the goal of increasing coverage for uninsured children does not supplant or overshadow the importance of ensuring that the receipt of health benefits coverage results in the provision of quality health care and improves health outcomes. Commenters believed that HCFA should consult with the States in creating these national standards, and in doing so, build upon the efforts of other Federal agencies, such as the performance measures developed for State Maternal and Child Health Services Block Grants by the Health Resources and Services Administration.

Response: We agree there should be a common core of evidence-based, standardized, child-related performance measures and performance goals. These measures and goals can be used to evaluate the overall effect of the program in access, service delivery, processes of care and health outcomes with the intent of improving the quality of care, particularly in the areas of well-baby care, well-child care, well-adolescent care, and childhood and adolescent immunizations. Section 2701(b)(1) of the Act and proposed § 457.20 directs that State plans must include assurances that the State will collect data, maintain records, and provide reports to the Secretary at the times and in the format the Secretary may require. The development of common quality and performance measures and goals is essential to assessing the national impact of the SCHIP program and we have modified the regulation text at § 457.710(d)(3) to provide that the Secretary may prescribe a common core of national measures.

However, we also acknowledge the difficulties in achieving national consensus on specified measures. Therefore, HCFA will convene a workgroup to develop a set of core performance measures and performance goals incorporating appropriate quality assurance indicators, and the methodology for implementing common measures and goals for SCHIP in an appropriate and timely manner. As we undertake this effort, we will be guided by the objectives, goals and measurement methods States have developed, as described in their annual reports and evaluations.

The development of national performance indicators and goals does not diminish the importance of having States identify their own specific strategic objectives, and accompanying performance goals and measurements. While States may be required to adopt national performance measures and goals once they have been developed, we expect States to implement their own performance measures, performance goals and strategic objectives specific to the unique design and priorities of their own program. States, in accordance with section 2107(a)(4) of the Act, will continue to be required under § 457.710 to establish State-specific performance measures and to describe how performance under the plan will be measured through objective, independently verifiable means and compared against performance goals.

Comment: One commenter suggested that HCFA recommend to States the following outcome measures: out-of-home placements, the Children and Adolescent Functional Assessment Scale (CAFAS), days-in-school, school performance, and reduced involvement in the legal system.

Response: We agree with the commenter that measures from a variety of sources can be useful in evaluating the impact of SCHIP on the health and the behavior of participants and we would encourage States to take them into consideration as they develop their State-specific performance measures. Additionally, as we convene a workgroup to discuss the development of national core performance and quality assessment measures, we will consider the measures the commenter has suggested. We are mindful, however, that SCHIP's first goal is to expand coverage to uninsured children and that, while it is generally believed that coverage and better access to health care can lead to improvements in school attendance and school achievement, it is difficult to isolate the cause and effect of changes in social behavior that are influenced by a wide range of factors and circumstances.

Comment: We received one comment expressing concern that the willingness and ability of managed care entities (MCEs) to participate in SCHIP depended on whether the revenues adequately covered the MCEs' costs. The commenter noted that costs associated with collecting and validating data may be substantial, and thus may prevent MCEs' from participation in the program. The commenter expressed concern that the MCE might not have a large enough population of SCHIP participants to generate statistically valid data. Additionally, the commenter asserted that HCFA has failed to establish realistic goals for Quality Improvement System for Managed Care (QISMC)-related health plan activities and performance that take into consideration available resources and responsibilities for the delivery of quality care for beneficiaries.

Response: We recognize the concerns expressed by the commenter. However, we disagree that the requirements in the proposed regulation may impose an undue financial hardship upon MCEs. This regulation provides States with significant flexibility regarding the performance measurements they will use and the preamble to the proposed rule encouraged States to review measures, including those widely used by private-sector purchasers of MCE services. We suggested in the preamble of the NPRM that States may wish to consider adopting standardized methods and tools in quality assurance and improvement, such as those of the QISMC initiative, but we did not propose and are not requiring the use of QISMC-related measures. However, the burden on MCEs would be minimized to the extent a State chooses measures that the MCEs are already using in connection with other programs.

In any event, the regulation imposes obligations on States and does not directly govern actions of MCEs. While we require States to report data relating to their strategic objectives and specific performance goals, we are aware of the difficulty in compiling statistically valid data in small sample sizes and are mindful of States' interest in reducing burden for their MCEs. The regulation does not require that States collect encounter data. States have the option of choosing other methods of collecting data related to their strategic objectives, including, but not limited to, surveys of SCHIP participants and/or SCHIP health care providers and looking at encounter data, to the extent it is available.

Comment: One commenter urged HCFA to include the American College of Obstetricians and Gynecologists educational bulletin entitled ''Primary and Preventive Health Care for Female Adolescents'' in the list set forth in the preamble of examples of widely recognized measures and guidelines states should review in developing performance measures for SCHIP programs.

Response: We agree with the commenter that there may be several measures beyond those we specifically mentioned in the preamble to the proposed rule that States might find helpful in translating their strategic

objectives into performance measures and goals. We encourage States to consider this bulletin as well as others that provide widely-used performance measures for children's and adolescent's health and health care.

Comment: A couple of commenters indicated that while the Health Employer Data and Information Set (HEDIS) was designed to be reported at the health plan level, plan-reported numerators and denominators can be added together to yield aggregate State-level reports that could help measure performance in reaching State enrollment targets and in delivering high quality health care. The commenters indicated that HEDIS measures are objective, validated measures of health plan performance (on quality, access and availability, and the use of services) and, when audited using the HEDIS Compliance Audit, performance measures are independently verified. In addition, the commenters stated that national benchmarks exist for both the commercial and Medicaid populations which can be used to establish performance goals and to evaluate performance of a specific health plan or State SCHIP program. One commenter noted that the National Committee on Quality Assurance (NCQA) offered to work with HCFA and States on implementation strategies, including making HEDIS specifications broadly available.

Response: We agree that HEDIS may be a useful tool for States in measuring their performance and establishing goals. We appreciate NCQA's willingness to assist with SCHIP implementation and are working with them to develop HEDIS specifications for SCHIP. In States that are considering using HEDIS measures, we have recommended the following approach to reporting data and information on SCHIP programs: Where a State contracts with managed care entities (MCEs) for health benefits coverage for SCHIP enrollees, States should, where possible, identify individual SCHIP enrollees for its contracting MCEs as detailed below.

If the State has identified SCHIP enrollees to a contracting MCE, and the contracting MCE also contracts with the State Medicaid program, then the MCEs should, as directed by the State either: (1) report the required HEDIS measures separately for SCHIP enrollees; or (2) include SCHIP enrollees in their Medicaid product line reports.

If the State has identified SCHIP enrollees to a contracting MCO and the contracting MCE is a commercial MCE without a Medicaid product line, the MCE should exclude SCHIP enrollees from its commercial product line reports, because including SCHIP enrollees in HEDIS reports for commercially enrolled populations may affect commercial MCE-to-MCE comparisons. Under these circumstances, HEDIS performance measures for SCHIP enrollees will need to be reported separately. In addition, MCEs with small numbers of eligible SCHIP enrollees should follow the small numbers general guideline. These specifications will be included in the HEDIS guidelines for 2001.

Comment: In response to HCFA's solicitation for comments on additional measures that will assist in articulating the success of programs implemented under title XXI, several commenters recommended the following performance measures:

Access

—Percentage of Medicaid eligible enrolled in Medicaid;
—Percentage of SCHIP eligible enrolled in SCHIP;
—Percentage of children with a usual source of health care;
—Percentage of children with an unmet need for physician services and/or delayed care;
—Reduction of hospitalization for ambulatory sensitive conditions;
—Percentage of enrollees who are enrolled for a year or more;
—Percentage of children who are identified as having special health care needs;
—Percentage of employers offering health insurance coverage to employees and dependent children;
—Percentage of enrollees whose parents decline employer-sponsored dependent health insurance coverage;
—Percent of children whose eligibility switches between title XIX and title XXI who enroll in the appropriate program (or who maintain health insurance coverage);
—Percentage of pediatricians, family physicians, and dentists who participate in Medicaid and SCHIP;

Process

—Percentage of children and adolescents who have received immunizations according to the ACIP/American Academy of Pediatrics recommended immunization schedule;
—Percentage of children and adolescents who have received all of the well-child visits appropriate for their ages, based on the American Academy of Pediatrics Recommendations for Pediatric Health Care;
—Percentage of adolescents ages 12 though 18 who were counseled for symptoms or risk factors for STDs;
—Percentage of children ages four through 18 during the reporting year who received a dental examination during that year;
—Percentage of children ages three through six who received a vision screening examination during the reporting year;
—Percentage of children and adolescents with all of the well-child visits provided at one health care site during the reporting year;
—Percentage of children and adolescents, parents or caretakers with difficulty communicating with health care professionals because of a language problem or difficulty understanding health care professionals;
—Percentage of children and adolescents with asthma who regularly use a peak flow meter during the reporting year, regularly use a spacer with a metered dose inhaler, and/or who received influenza vaccine during the reporting year;
—Percentage of children with special health needs who received care during the reporting year;

Outcomes

—Rate of hospitalization for ambulatory sensitive conditions such as asthma, diabetes, epilepsy, dehydration, gastroenteritis, pneumonia; or urinary tract infection (UTI);
—Rate of hospitalization for injuries;
—Percentage of children and adolescents reporting days lost from school due to health problems;
—Percentage of children reporting risky health behaviors including injuries, tobacco use, alcohol/drug use, sexual behavior, poor dietary behavior, lack of physical activity;
—Percentage of adolescents reporting attempted suicides;
—Percentage of children reporting unmet medical needs;
—Percentage of children reporting unmet vision needs;
—Percentage of children reporting unmet dental needs; and
—Percentage of family income used for medical and dental care.

Response: Assessments of the impact of the title XXI program on children's health insurance coverage, access to care and use of health care services will occur on both the State level and national levels. On the State level, we would encourage States to consider the commenters' suggested performance measures as they identify those measures which are appropriate for each

of their strategic objectives as required under section 2107(a)(3) of the Act and § 457.410(b).

Nationally, as HCFA works to develop a common core of standardized child-related performance measures, performance levels and quality measures that can be used to evaluate access, service delivery, processes of care, health outcomes and quality in the overall SCHIP program, we will consider the performance measures recommended by the commenters.

3. State Plan Requirement: State Assurance Regarding Data Collection, Records, and Reports (§ 457.720)

Section 2107(b)(1) of the Act requires the State plan to provide an assurance that the State will collect the data, maintain the records, and furnish the reports to the Secretary, at the times and in the standardized format that the Secretary may require to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans under title XXI. We proposed to implement this statutory provision at § 457.720.

We did not receive any comments on this section and are therefore implementing the provision as proposed.

4. State Plan Requirement: State Annual Reports (§ 457.730)

Section 2107(b)(2) of the Act discusses the requirement that the State plan include a description of the State's strategy for the submission of annual reports and the State evaluation.

Accordingly, we proposed to implement this provision at § 457.730. We noted that, in order to facilitate report submission, a group of States worked with staff from the National Academy of State Health Policy (NASHP), with HCFA representation, to develop an optional model framework for the State evaluation due March 31, 2000 and for subsequent annual reports. We also noted that we would permit States to submit their FY 1999 annual report and their State evaluation on March 31, 2000, together as one comprehensive document. However, since the States evaluations/annual reports have all been submitted, this provision is unnecessary and has been deleted from the final rule. In addition, we have moved the discussion of the annual report requirements to comments and responses on § 457.750.

Comment: One commenter recommended that we require States to use a designated framework for submitting annual reports and evaluations. This commenter suggested that we include clinicians, child advocates and research groups to participate in the development of frameworks for future reports.

Response: While we do not believe it is necessary to require a designated framework for annual reports and evaluations, in order to facilitate report submission, a group of States worked with staff from NASHP and with representatives from HCFA to develop an optional model framework for the State evaluation due March 31, 2000. This framework was finalized and sent to every State and territory with an approved State plan. All States that have submitted their State evaluations have voluntarily used this framework as the basis for their evaluation, although several States supplemented their evaluations with additional data. We currently are in the process of analyzing and synthesizing the data submitted in these evaluations. We will continue to work with States and other interested parties to support these efforts to promote ease of reporting and to facilitate analysis and comparison of important data reported by States on their programs.

NASHP has subsequently developed a similar framework for the annual reports that States will be submitting in January 2001. As SCHIP development continues, we encourage continued participation in the evaluation process by interested researchers, health care providers and provider groups, advocates and advocacy groups, insurance providers, State and local government officials, and other interested parties and intend to keep the process as open and collaborative as possible.

5. State Expenditures and Statistical Reports (§ 457.740)

We proposed to require that the States collect required data beginning on the date of implementation of the approved State plan. We proposed that States must submit quarterly reports on the number of children under 19 years of age who are enrolled in separate child health programs, Medicaid expansion programs, and regular Medicaid programs (at regular FMAP) by age, income and service delivery categories. In the preamble, we noted that the Territories are excepted from the definition of ''State'' for the purposes of quarterly statistical reporting. We also proposed to require that thirty days after the end of the Federal fiscal year, the State must submit an unduplicated count for that Federal fiscal year of children who were ever enrolled in the separate child health program, the Medicaid expansion program and the Medicaid program as appropriate by age, service delivery, and income categories.

We proposed that the age categories that must be used to report the data are: under 1 year of age, 1 through 5 years of age, 6 through 12 years of age, and 13 through 18 years of age. We further proposed to require States to report enrollment by the service delivery categories of managed care, fee-for-service, and primary care case management.

We noted in the proposed regulation and explained in the preamble that States must report income by using State-defined countable income and State-defined family size to determine Federal poverty level (FPL) categories. We proposed that States that do not impose cost sharing and States that only impose cost sharing based on a fixed percentage of income (such as 2 percent) in their Medicaid expansion program or their separate child health program must report their SCHIP and Medicaid enrollment by using two categories: at or below 150 percent of the FPL and over 150 percent of FPL. States that impose cost sharing at defined income levels (for example, at 185 percent and over of FPL) in their Medicaid expansion programs and/or separate child health programs would be required to report their Medicaid and SCHIP enrollment by poverty level (that is, countable income and household size) categories that match their Medicaid expansion program and separate child health program cost-sharing categories. We proposed to require enrollment reporting by income for Medicaid as well as for SCHIP.

We proposed that required standardized reporting be limited to expenditure data and enrollment data as reported by age, poverty level, and service delivery category. We noted in the preamble to the NPRM that States should collect other relevant demographic data on enrollees such as gender, race, national origin, and primary language and that collecting such data will encourage the design of outreach and health care delivery initiatives that address disparities based on race and national origin.

We stated that we were working to develop an option for States to provide the needed SCHIP data through existing statistical reporting systems in the future.

Comment: One commenter suggested that we revise the regulations to specify that a State's failure to submit the statistical reporting forms would ordinarily be considered substantial non-compliance.

Response: Section 457.720 requires States to comply with data reporting

requirements. Section 2106(d)(2) of the statute and § 457.204(c) provide the Secretary with authority to enforce these and other requirements. We do not believe that it is necessary to specify more specific sanctions for non-reporting or delayed reporting within the rule.

We are working closely with States to develop and implement data tracking and reporting systems. SCHIP reporting may involve creating new systems or adjusting existing systems to collect data which can then be reported to DHHS and we recognize that the reporting changes required in this final rule may require further changes to these systems. We will work with the States to accommodate individual needs for technical assistance during the transition.

In the past, some States have had difficulty reporting data to us in a timely matter due to systems constraints. However, we anticipate that many of these difficulties will be resolved in the near future. We recently implemented a new, more easily accessible web-based data reporting system (the Statistical Enrollment Data System (SEDS)) that all States can access through the Internet, rather than through the main frame system. We have also revised the reporting instructions to clarify definitions in a way that will be more clear for States and provide for more standardized reporting among the States. We released these new instructions with a letter to State Health Officials on September 13, 2000. In addition, we are continuing a comprehensive evaluation of possible modifications to the Medicaid Statistical Information System (MSIS), which captures State eligibility and claims records on a person-level basis. The modifications will give States the option of using MSIS to supply the data elements that will meet the title XXI quarterly statistical reporting requirements. We look forward to working with States to further improve the time lines and quality of required SCHIP data. In addition, we have added a new reporting line to the quarterly reports where States indicate a ''point in time'' enrollment count that indicates enrollment as of the last day of the quarter for their SCHIP and title XIX Medicaid programs. This count is something the States already have available for their own purposes and helps provide a more complete picture of States' programs on an ongoing basis.

Comment: We received several comments requesting that HCFA require States to collect data pertaining to one or more of the following categories of information about enrollees and their SCHIP coverage: gender, ethnicity, race, primary language, English proficiency, age, service delivery system, family income, and geographic location. Certain commenters suggested that this data be collected and reported to HCFA in the State evaluations, annual reports, and/or quarterly statistical reports. These commenters felt this information would help target outreach, retention, enrollment, and service efforts to under-represented groups. These commenters also indicated that such reporting requirements are consistent with the goals of Healthy People 2010 and recently enacted legislation directing the Secretary of Commerce to produce statistically reliable annual State data on the number of uninsured, low-income children categorized by race, ethnicity, age, and income. One commenter indicated that HCFA should require States to document the appropriate range of services and networks of providers available, given the various language groups represented by enrollees. Additionally, some commenters noted that HCFA should require States to provide an assessment of their compliance with civil rights requirements.

Response: We agree with several of the comments summarized above. Section 2107(b)(1) of the Act requires that ''a State child health plan shall include an assurance that the State will collect the data, maintain the records and furnish the reports to the Secretary, at the times and in the standardized format the Secretary may require in order to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans.'' The proposed rule at § 457.740(a) had included requirements on States to collect and submit data by age categories, service delivery categories and by countable income. In an effort to streamline data reporting requirements, we had only encouraged States to collect data with respect to gender, race and ethnicity, and did not propose to require the collection or the reporting to HCFA of such data. We received many comments expressing concern about this policy and urging us to require States to report data on gender, race, ethnicity and primary language of SCHIP enrollees to HCFA.

We have reviewed our proposed policy and have decided that it is consistent with overall program goals, as well as the civil rights requirements, to require States to report data, on a quarterly basis, on the race, ethnicity, and gender of SCHIP enrollees using the format prescribed by the OMB Statistical Directive 15—Standards for the Maintaining, Collecting and Presenting Data on Race and Ethnicity. We have therefore amended § 457.740(a)(2) to reflect this requirement. Because primary language of SCHIP enrollees is not one of the data elements on standardized reporting formats, we will require States to report on this information as part of the Annual Report, and have amended § 457.750(b)(8) to reflect this change. We understand that nearly all States have already been collecting this information through the application process. Although States may request information on gender, race, ethnicity and primary language at the time of application, States may not require families to report this data as a condition of application to, or enrollment in the SCHIP program. The information must be collected from SCHIP applicants and enrollees on a voluntary basis. Having this data will enable States and the Department to see how and if minority children and other categories of children are being covered by the SCHIP program and to identify opportunities for more effective outreach and retention strategies.

Furthermore, required reporting of this data is consistent with Departmental priorities to more effectively identify racial disparities in the provision of health care and to assure that language barriers do not interfere with children's ability to secure health care. HCFA will modify its data base to permit States to report these data on the same system as they report enrollment data. We understand States may incur additional administrative costs to comply with this requirement. However, the potential benefits for the States and for the Department are significant.

Comment: Commenters asserted that neither the State nor the health insurance purchasing cooperative has the legal authority to require employer-sponsored insurance carriers to report claims data. Therefore, commenters noted, States with premium assistance programs would have difficulty reporting program expenditures and participants by age, income, delivery system, and program type as required by HCFA.

Response: Since States or their contractors would be completing the eligibility process for children enrolling through premium assistance programs, States would have data available on the child's age, family income, the type of child health insurance program offered by the State, and the expenditures being made on behalf of the child. We are not requesting individual claims data used by group health plans providing SCHIP

coverage. Service delivery systems could be ascertained by the State by reviewing the benefit package available through each employer. This might present difficulties if an employer had several options with varying delivery systems available at the same cost to the State. Should this be the case, we would work with States on a case-by-case basis to consider other options for collecting this data.

Comment: One commenter noted that the collection report Form HCFA–64, revised in December 1998, requires additional information that is not reflected in § 457.740, including number of months enrolled, and the number disenrolled per quarter. Several commenters suggested that HCFA require States to report this data to HCFA on a quarterly basis.

Response: In § 457.740, we did not intend to specify each data element that we will be requiring, because we wanted to be able to review and modify specific elements as the program evolves. We have authority under section 2107(b)(1) to specify at § 457.720, that States must provide data ''at the times and in the standardized format * * *'' to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans under title XXI. This includes the number of months enrolled and number disenrolled per quarter.

The forms referenced by the commenter are quarterly reports used by State Medicaid agencies to report to HCFA their actual Medicaid expenditures and the numbers of SCHIP children and other children being served in the Medicaid program. HCFA uses these forms to ensure that the appropriate level of Federal payments for the State's Medicaid expansion program expenditures, and to track, monitor and evaluate the numbers of SCHIP children being served by the Medicaid expansion program. HCFA uses a similar quarterly reporting form, the HCFA–21, to collect comparable information on separate child health programs.

Comment: One commenter noted that the collection of data to measure the effectiveness of SCHIP should include the number and types of services actually delivered in addition to the number of children enrolled. This commenter suggested that we revise the regulations to specify that data can be collected and reported by the State using American Dental Association procedure codes to reflect total number of actual services rendered to eligible individuals.

Response: We agree States should consider utilization measures in developing Statewide performance measures of progress toward meeting State performance goals and strategic objectives. We also envision that States may want to measure care and service delivery so that they may determine numbers of participating providers and health networks needed for the program. The regulation provides States with flexibility in developing these measures and appropriate data collection methodologies.

As the Department works on developing and implementing a common core of standardized performance measures and performance goals, we will consider the outcome measures suggested by the commenter.

Comment: One commenter generally supported the quarterly reporting requirements but requested one additional required report measure. Specifically, the commenter urged HCFA to require reporting (either annually or quarterly) on the number of newborns who are enrolled at birth and the number of infants who are enrolled within the first three months of life. The commenter believed this information could be used by States to assess whether income-eligible newborns are experiencing gaps in coverage between the time of birth and SCHIP enrollment.

Response: We strongly encourage the States to collect the required information on age of participants in such a way that they may analyze the health coverage patterns of newborns and infants. We have not required States to report this information to HCFA. However, we will consider the commenter's suggestion as we develop the national core set of performance measures and goals.

Comment: One commenter urged HCFA to require States to describe their income calculation methodologies and changes in those methodologies and to make that information available to the public.

Response: We agree with the commenter's suggestion and note that income calculation methodologies and changes to these methodologies were requested to be provided by States as part of their State evaluations (due to HCFA on March 31, 2000). Because of the importance of having this information in a standardized manner, as well as keeping the information current, we have included this as an element of subsequent State annual reports. We have compiled and reviewed the submissions from the States thus far, and the information is available to the public along with the rest of the States' evaluations on the HCFA web site.

In addition, we discussed in our July 31, 2000 guidance on SCHIP section 1115 demonstrations that in order to receive approval for a demonstration proposal, States must have submitted all of their required statistical reports and evaluations to HCFA, dating back to the implementation of their program.

Comment: One commenter found the detailed reporting requirements problematic, cumbersome, and difficult to comply with under current automated systems.

Response: We recognize the commenter's concerns. However, we will continue to require the collection and quarterly reporting to HCFA of the data required in this section. We will continue to offer technical assistance to States having difficulty reporting the required data due to automated system difficulties. As noted previously, States are able to report data to HCFA through a web-based reporting system on the Internet, to provide States with easier access to the reporting system. In addition, we have developed a set of revised reporting instructions to facilitate reporting by States in a standardized format. We believe these modifications will result in a reporting system with which States can comply with minimal difficulties.

In addition, we are continuing a comprehensive evaluation of possible modifications to the Medicaid Statistical Information System (MSIS), which captures State eligibility and claims records on a quarterly basis. The modifications will give States the option of using MSIS to supply data related to separate child health programs as well as Medicaid expansion programs and will promote overall consistency among SCHIP and Medicaid data in the long term.

Comment: We received several comments applauding our recognition of the interrelationship of Medicaid and SCHIP and the requirement of similar reporting for regular Medicaid, Medicaid expansion, and separate child health programs. However, one commenter opposed the requirement that all States, including those operating separate child health insurance programs, report changes in enrollment in both the SCHIP program and the Medicaid program. The commenter noted that some States operate separate child health programs that are administered by different staff, governing boards, budgets, etc. than the State Medicaid program. The commenter opposed a requirement that a separately administered SCHIP program have a contractual requirement

to obtain data from a Medicaid agency. The commenter stated that if HCFA wished to review Medicaid data, it should develop new Medicaid regulations to require such data and to provide reimbursement to the Medicaid agency as the SCHIP program has no budget or legal authority to collect Medicaid data. The commenter added that additional administrative requirements from HCFA should be accompanied by additional administrative dollars, or they represent unfunded mandates that exacerbate the 10 percent administrative-cost limit problem.

Response: The statute anticipates that State agencies implementing SCHIP and Medicaid will coordinate activities and share information. Section 2108(b)(1)(C) of the Act requires States to report on or before March 31, 2000 ''an assessment of the effectiveness of other public and private programs in the State in increasing the availability of affordable quality individual and family health insurance for children.'' In addition, section 2108(b)(1)(D) specifically requires States to report on coordination with other public and private programs providing health care and health financing, including Medicaid programs. Furthermore, these requirements are not specific to the State agency administering SCHIP or Medicaid, but rather apply to the State as a condition of receiving grant funding under these programs, regardless of how the State internally delegates responsibilities under these programs.

In addition, section 2107(b)(1) of the Act requires that the State plan contain certain assurances regarding the collection of data and submission of reports to the Secretary. In addition, § 431.16 of the Medicaid regulations specifies that a State plan must provide that the Medicaid agency will submit all reports required by the Secretary, follow the Secretary's instructions with regard to the format and content of those reports, and comply with any provisions that the Secretary finds necessary to verify and assure the correctness of the reports. These statutory and regulatory provisions serve as our authority for requiring Medicaid State expenditure and statistical reporting at § 457.740. State agencies can reasonably be expected, as directed in the statute, to coordinate among programs, including by sharing and reporting information.

Since Medicaid agencies receive Federal financial participation under title XIX for administrative costs, such as those associated with data collection, sharing this information with the States' title XXI programs should not exacerbate any difficulty States may have in staying within the 10 percent administrative cost limit in SCHIP.

6. Annual Report (§ 457.750)

Section 2108(a) of the Act provides that the State must assess the operation of the State child health plan in each fiscal year, and report to the Secretary, by January 1 following the end of the fiscal year, on the results of the assessment. In addition, this section of the Act provides that the State must assess the progress made in reducing the number of uncovered, low-income children. We proposed to implement the statutory provision requiring assessment of the program and submission of an annual report at § 457.750(a).

At proposed § 457.750(b), we set forth the required contents of the annual report. Specifically, in accordance with the statute, the annual report must provide an assessment of the operation of the State plan in the preceding Federal fiscal year including the progress made in reducing the number of uncovered, low-income children. In addition, we proposed to require that the State report on: (1) progress made in meeting other strategic objectives and performance goals identified by the State; (2) successes in program design and implementation of the State plan; and (3) barriers in program design and implementation and the approaches under consideration to overcome these barriers. We also proposed to require that the State report on the effectiveness of its policies for discouraging the substitution of public coverage for private coverage. Further, we proposed to require that the annual report discuss the State's progress in addressing any specific issues, such as outreach, that it agreed to monitor and assess in its State plan.

In accordance with section 2107(d) of the Act, we also proposed that a State must provide the current fiscal year budget update, including details on the planned use of funds for a three-year period and any changes in the sources of the non-Federal share of plan expenditures. We also proposed that the State must identify the total State expenditures for family coverage and total number of children and adults covered by family coverage during the preceding Federal fiscal year.

We proposed that, in order to report on the progress made in reducing the number of uncovered, low-income children in the annual report, a State must choose a methodology to establish an initial baseline estimate of the number of low-income children who are uninsured in the State and provide annual estimates, using the chosen methodology, of the change in this number of low-income uninsured children at two poverty levels: 200 percent FPL and at the current upper eligibility level of the State's SCHIP program. We noted in the preamble to the proposed rule that, in making these estimates, a State would not be required to use the same methodology that it used in identifying the estimated number of SCHIP eligibles in the State plan.

We proposed to require that a State base the annual baseline estimates on data from either: (1) The March supplement to the Current Population Survey (CPS); (2) a State-specific survey; (3) other statistically adjusted CPS data; or (4) other appropriate data. We also proposed that a State must submit a description of the methodology used to develop these estimates and the rationale for its use, including the specific strengths and weaknesses of the methodology, unless the State bases the estimate on the March supplement to the CPS. We indicated in the preamble to the proposed rule that, once a State submits a specific methodology in the annual report for estimating the baseline numbers, the State must use the same methodology to provide annual estimates unless it provides a detailed justification for adopting a different methodology. We also noted therein that traditionally, most national estimates of uninsured children have been based on the Bureau of Census March Current Population Survey (CPS). We further noted in the preamble that, as the only data source with the capacity to generate State-by-State estimates of uninsured children, the CPS generally is relied upon by policy makers to provide an overall estimate of insurance status and insurance trends in the nation. We also mentioned other major surveys that provide insight into the number of uninsured Americans.

Comment: One commenter recommended that we require annual reports to contain reasonable utilization measures indicating quality and access to care for children with special needs in addition to the general child population. The commenter believed that the Secretary should conduct a focused study of children with special needs. Another commenter noted that States providing dental benefits should report annually on the assistance provided to recipients in accessing needed services.

Response: We are very concerned about services for special needs children, and we agree with the commenters that quality and access are important both with respect to special needs and dental benefits and States are encouraged to address these important

areas in their annual reports. However, requiring such reporting would be inconsistent with the flexibility permitted under the statute. At § 457.495(b) of this final rule, we require States to provide assurances of appropriate and timely procedures to monitor and treat enrollees with chronic, complex or serious medical conditions, including access to specialists experienced in treating the specific medical condition. We leave it to the States to determine what systems and procedures they will implement to ensure enrollees with such conditions have access to quality care consistent with this standard.

In order for States to create systems which fit their unique programs, the methodology for complying with § 457.495 is best left to the State. Reporting on access to dental benefits is subsumed under § 457.495(a), which requires States to include in their plans a description for assuring the quality and appropriateness of care provided under the plan including access to covered services listed in § 457.402(a). Dental services is one of the optional services States may cover under the definition of child health assistance located at § 457.402(a)(16). To the extent that States cover dental services in their SCHIP plans, they must assure access to those services. Therefore, we have not adopted the commenter's suggestion to add a separate requirement regarding dental services.

Comment: One commenter asserted that HCFA exceeds its authority in the annual report requirements at § 457.750(c) that requires States to provide a rationale and description of the methodology used to establish the baseline estimate, if the estimate is based on a source other than the CPS. The commenter contended that the purpose of the annual report is for States to assess the operation of their programs. The commenter also argued that HCFA lacked authority to compel States to adopt the CPS standard. The commenter referred to section 2108 of the Act, which provides that the State shall assess its performance and submit that assessment to the Secretary. The commenter noted that providing a rationale for a methodology made States take additional steps that were not prescribed by the statute. In requiring this rationale, the commenter suggested HCFA came perilously close to dictating the CPS standard, which violates the express terms of title XXI and Executive Order 13132, regarding Federalism. The commenter indicated that under Executive Order 13132, HCFA is required to justify the imposition of any national standard and to look for less burdensome alternatives. The commenter expressed the view that the proposed rule improperly shifts the burden of justifying standards used to evaluate programs from HCFA to the States.

Response: Section 2107(b)(1) of the Act expressly gives the Secretary the authority to require data collection, records maintenance, and reports from the States ''at the times and in the standardized format the Secretary may require in order to enable the Secretary to monitor State program administration and to evaluate and compare the effectiveness of State plans.'' In order to effectively monitor State program effectiveness in reducing the number of uninsured children, the method of detecting the numbers of uninsured in States and the decline or increase in the uninsured must be known and understood in a standardized manner when possible. The statute uses CPS for formula allocating, so it was suggested as the best available source for State uninsurance levels among low-income children. Most States elected to use the CPS in establishing their initial baselines. However, we recognize the shortcomings of CPS for many States and have therefore provided flexibility to use other sources, both initially and prospectively. The requirement that States explain their alternative methodology is necessary and appropriate in order for HCFA to be able to identify and assess the data provided by States. In addition, we have further clarified that if States elect to use a different data source in re-establishing a baseline, the State must also note in the annual report the CPS estimate for that year, both as a means of providing standardized information across States, using a consistent baseline and to ensure that States are given credit for progress in enrolling children back to the beginning of their programs.

Comment: One commenter requested that HCFA allow States to use biennial State survey figures in assessing changes in uninsurance rather than the annual figures from the CPS. The commenter noted that the CPS data is unreliable for its State and administering an annual survey would be cost-prohibitive for some States.

Response: Section 457.750(c)(1)(ii) provides that a State may base its estimate of the number of uninsured, low-income children from a State-specific survey. Thus, States may use biennial data from State surveys, utilizing statistically relevant adjustments in the off-survey year or by supplementing the biennial data with additional State-specific data from other sources to fulfill the annual reporting requirements of this section. We note that, as stated in the previous response, States will be required to provide a description of the methodology and rationale for using the State-specific survey, in accordance with § 457.750(c)(2).

Comment: One commenter urged HCFA to revise the proposed rule to reflect provisions of the Balanced Budget Refinement Act of 1999 (BBRA), which require that the March Supplement of the CPS be expanded to allow State-level estimates of the number of uninsured children. The commenter believed that using these updated estimates would be preferable to allowing States to establish their own methodologies for estimating the number of uninsured children.

Response: We note that provisions of section 703(b) of BBRA amended Section 2109 of the Act to modify the March Supplement of the CPS to detect real changes in uninsurance rates of children. The BBRA requires future modifications to the Current Population Survey in order to produce statistically reliable annual State-level data on the number of low-income children without health insurance coverage. One modification to the CPS is to include data on children by family income, age, and race, and ethnicity. Adjustments to be made include expanding sampling size used in State sampling units and expanding the number of sampling units in a State. Therefore, with the creation of this requirement, Congress sought to help provide all States with access to more reliable State-level data on the uninsured population through the CPS March Supplement. We have not modified the regulation text to reflect this change, as this data is not expected to be available until October or November 2001. We wanted to leave the regulation text open to future improvements to the CPS or other data sources. Even with the CPS adjustments, there are States that believe they can provide more accurate estimates of the level of uninsured children in their State with methodologies that use other data sources or sources that supplement the CPS data. We believe it is important to allow States this flexibility in developing the most reliable estimate for their State.

Comment: One commenter supported the required collection of information in the annual report, and recommended we require States to also report on the following information in the annual reports:

—Progress in addressing the barriers to access experienced by minority children;

—Grievances, complaints of problems reported relating to enrollment, access, and quality of care as a means of measuring consumer satisfaction, ensuring they are adequate to resolve complaints within a reasonable time frame and that plans use grievance and complaint data to improve quality;
—Cultural competency measures;
—Continuity of care between plans, providers, or programs;
—Special attention to under-served or under-identified populations (for example, homeless children);
—Systematic integration with schools and other community groups;
—Whether primary care and pediatric specialty care capacity is adequate for the number of enrollees;
—Whether plans meet standards for access within reasonable time frames;
—Whether care is in accordance with clinical practice guidelines for quality of care; and
—The proportion of providers who are both Medicaid and separate SCHIP providers among those serving Medicaid and separate SCHIP beneficiaries, and the difference in payment rates to plans or providers in Medicaid and separate SCHIP programs.
—Estimates of the number of uninsured children under the regular Medicaid income thresholds as well as those under the 200 percent FPL and under the State's SCHIP income threshold;
—Data on the method of application for Medicaid and SCHIP (mail-in, outstation-site, Internet, etc.) and enrollment procedures for each program;
—Data on the portion of applicants denied and reason for denial;
—Number of children disenrolled for any reason, the reason for disenrollment, and the number of children disenrolled for nonpayment of premiums;
—Number of children continuously enrolled in Medicaid and/or separate SCHIP program for one year or more;
—Number of children identified by screening as Medicaid eligible and, of those, the number enrolled in Medicaid;
—Number of former Medicaid recipients enrolled in separate SCHIP;
—Data on the number of applicants denied eligibility and the reason for the denial, including that they were disqualified due to current insurance coverage as well as the number of children disqualified due to insurance coverage in a past period, where applicable;
—Number of children who lose coverage at redetermination and the reason for loss of coverage; and
—Data comparing the proportion of children enrolled and using services by gender, race, ethnicity, and primary language to the proportion of such children in the service area.

Response: As noted earlier, HCFA participated in a workgroup led by the National Academy of State Health Policy to develop a template for States' annual reports that have provided an opportunity for States to report the information required in § 457.750 in a standardized way. NASHP released this template to the States and the public in November 2000 for States to use in completing their annual reports for FY 2000. In addition to budget and expenditure data, this will include information from States on their progress in reducing the number of uninsured low-income children, meeting strategic goals and performance measures, the effectiveness of States' policies for preventing substitution of coverage, and identifying successes and barriers in the States' plan design. In addition, the reports provide a forum for evaluating States' progress in addressing specific issues (such as outreach) and the primary language of SCHIP enrollees. We will work with NASHP to include these elements in a revised version of the annual report framework upon publication of this final rule. States will not be expected to address these new elements until they submit their FY 2001 reports. In addition, because the information can be more appropriately displayed in the annual report than in the quarterly reports, we have added a new § 457.750(b)(7) to require States to provide information on primary language of SCHIP enrollees in their annual reports. HCFA will continue to closely review the data collected and reported by the States in their annual reports.

We note that many of these assessment elements were provided by States in their State evaluations. Specifically, as part of the evaluation, States were required, as specified in section 2108(b)(1) of the Act and laid out in the NASHP evaluation framework, to provide information on baseline numbers of uninsured low-income children in the State by income level; levels of previous insurance coverage for applicants and enrollees; and quarterly enrollment statistics including: number of children ever enrolled; new enrollment; number of member months enrolled; average months enrolled; disenrollment including the reasons for disenrollment; unduplicated count of enrollment; and enrollee characteristics, such as income. Many States provided additional information on enrollees' gender, race and ethnicity in the reports. The annual report template is not as extensive as the evaluation template, but many of the same elements are included. Therefore, States will have the ability to indicate in subsequent annual reports that no update is needed since the evaluations were submitted.

Finally, it should be noted that, as we work toward developing and implementing a national core set of performance measures and goals, we will consider the performance goals suggested by the commenters.

Comment: One commenter noted that the preamble to proposed § 457.750(c)(1) was unclear as to whether the program referred to in the phrase ''upper eligibility level of the State's program'' is Medicaid or SCHIP.

Response: The requirements of subpart G of the regulations regarding strategic planning, reporting, and evaluation apply to separate child health programs and Medicaid expansion programs. Thus, in § 457.750(c)(1), we are referring to the upper eligibility level of the State's SCHIP program, which would be the upper eligibility level of either a Medicaid expansion or a separate child health program. If a State operates a combination program, the upper eligibility level would be the highest eligibility level of either the Medicaid expansion or the separate program.

Comment: One commenter recommended that specific measures be defined either for all SCHIP programs or separately for employer-sponsored insurance model programs based on HEDIS or Healthy People 2000 guidelines, to ensure that all States report similar guidelines and that common agreements could be used across States. Given that some States plan to use an employer-sponsored insurance model for coverage, the commenter suggested that HEDIS measures would seem the most appropriate approach on which to base data collection and reporting systems. For States using an employer-sponsored insurance model, contracts or agreements between the State and carriers would be needed for collection and data provision, this commenter stated. In this commenter's view, States would have to create specific data collection and reporting mechanisms to do this.

Response: The regulations do not require States, including States with premium assistance programs, to collect data on specifically defined measures, except with respect to any core set of performance measures that may be developed by the Secretary at a later

date. We encourage States to work with health plans, HCFA, and each other to create standards that meet their mutual needs for data. We particularly encourage States using premium assistance program models for SCHIP to explore effective methods of data collection, but recognize that data collection will present particular challenges to these types of programs because the State may not have direct contractual relationships with employer group health plans or with health insurance issuers offering group health insurance coverage. States may need to explore alternative methods of data collection for premium assistance programs, such as consumer surveys and polling.

Comment: One commenter expressed concern that the requirement at § 457.750(b)(5) stating that the annual report must include an updated budget is unnecessary and duplicative of other ongoing requirements, including the HCFA form 37, ''Medicaid Program Budget Report—State Estimate of Quarterly Grant Award.''

Response: The requirement for updated budgets in the annual report is necessary for the sound administration of SCHIP. Annual reporting of updated budgeting with three-year projections, including changes in sources of non-Federal funding and details on the planned uses of all funds, is essential to sound financial management of this program. Annual updated reports are also essential to HCFA as it monitors and anticipates the financial needs of States implementing SCHIP programs. Because States have up to three years to spend each annual allotment, a three-year budget is useful to show if States are planning to use their unused allotments in the succeeding two fiscal years or if they anticipate a shortfall in Federal funding. Therefore, we have decided to retain this requirement for a three-year budget in the final regulation. However, we are no longer requiring a three-year budget with all amendments. Instead, we have limited the requirements at § 457.80 to a one-year budget only with amendments that have a significant budgetary impact. A more detailed discussion of this issue can be found in the comments and responses to § 457.80.

Comment: One commenter noted that in § 457.750(b)(5) of the proposed rule, States are required to include in the annual report an updated budget for the current Federal fiscal year. The commenter states that HCFA did not take into account the State appropriations process and the fiscal year used by the State as opposed to the Federal fiscal year. For example, Illinois has a July-June fiscal year, with the legislature appropriating funds for the final Federal quarter (July-September) in May. Therefore, the commenter noted, the last quarter in the SCHIP annual report will be an estimate. The commenter believed that the regulations regarding the annual report should be revised to permit States to estimate budgets for the final Federal quarter.

Response: We have modified § 457.750(b)(5) as proposed. Instead of requiring an annual budget for the current fiscal year, we now require an annual updated budget for a three-year period. We realize that the three-year budgets States are required to submit annually in fulfilling the requirements of § 457.750(b)(5) are based on projections and may vary from actual expenditures for a variety of reasons. However, we believe it is important to have this information to ensure that States have adequately planned for the program and to analyze spending allotments.

7. State Evaluations (§ 457.760)

In proposed § 457.760 we set forth the requirement that States submit a comprehensive evaluation by March 31, 2000 that analyzes the progress and effectiveness of the State child health program. In the evaluation, a State must report on the operation of its Medicaid expansion program, separate child health program, or combination program. As specified in section 2108(b)(1)(B) of the Act, the State evaluation must include all of the following:

- An assessment of the effectiveness of the State plan in increasing the number of children with creditable health coverage. In addition, the State must report on progress made in meeting other strategic objectives and performance goals identified by the State plan.
- An assessment of the State's progress in meeting other strategic objectives and performance goals identified by the State plan.
- A description and analysis of the effectiveness of elements of the State plan, including the following elements:
  - —The characteristics of the children and families assisted under the State plan, including age of the children and family income. The State also must report on children's access to, or coverage by, other health insurance prior to the existence of the State program and after eligibility for the State program ends (the child is disenrolled). As an optional strategy, the State also should consider reporting on other relevant characteristics of children and their families such as sex, ethnicity, race, primary language, parental marital status, and family employment status.
  - —The quality of health coverage provided under the State process or other process that is used to assure the quality and appropriateness of care.
  - —The amount and level of assistance including payment of part or all of any premiums, copayments, or enrollment fees provided by the State.
  - —The service area of the State plan (for example, Metropolitan Statistical Area (MSA) or non-MSA).
  - —The time limits for coverage of a child under the State plan. As an optional strategy, the State should consider reporting the average length of time children are assisted under the State plan.
  - —The extent of substitution of public coverage for private coverage and the State's effectiveness in designing policies that discourage substitution.
  - —The State's choice of health benefits coverage, including types of benefits provided and the scope and range of these benefits, and other methods used for providing child health assistance.
  - —The sources of non-Federal funding used in the State plan.
- An assessment of the effectiveness of other public and private programs in the State in increasing the availability of affordable quality individual and family health insurance for children.
- A review and assessment of State activities to coordinate the SCHIP plan with other public and private programs providing health care and health care financing, including Medicaid and maternal and child health services.
- An analysis of changes and trends in the State that affect the provision of accessible, affordable, quality health insurance and health care to children.
- A description of any plans the State has for improving the availability of health insurance and health care for children.
- Recommendations for improving the SCHIP program.

Comment: One commenter indicated that the State evaluation requirements should be less prescriptive and require an analysis of the effectiveness of elements the State may include rather than requiring an analysis of all eight elements listed at § 457.760(c). The commenter asserted that such policy would allow States to identify and address areas relevant to their own State plans. The commenter suggested that we revise this section to provide that ''a description and analysis of elements of the State plan *may* include:'' the elements in paragraph (c) of this section.

Response: States were statutorily required to report on the progress of the elements set forth in § 457.760(c) in the State evaluation, due to HCFA on March 31, 2000, and we modeled the proposed regulation text after the statute. Section 2108(b) of the Act specifies the contents of the State evaluation. HCFA therefore does not have discretion to make these requirements optional for States. In addition, because all the States have submitted the required evaluation, we have removed this provision from the final rule. Any request for future evaluations will be based upon the requirements in the statute for evaluations and annual reports on the program.

Comment: We received several comments expressing appreciation that the guidance set forth in the preamble to the proposed rule regarding the evaluation closely followed the evaluation framework developed by NASHP and the State workgroup. However, several commenters asserted that the information provided in State evaluations should not be used to establish model programs and practices. Rather, they noted, States should be given the freedom to design programs that best suit the needs of their population and circumstances, and information provided in the evaluation should focus on how the States have used the flexibility allowed by the program to create unique and successful plans.

Response: We are using the evaluations to identify model practices. We believe that the identification of model practices should not involve comparing unlike programs or overlooking the unique circumstances of each State. Many States have been eager to learn about other State practices. We envision model practices as a means of sharing information with States and other interested parties on how other States have successfully implemented certain parts of their program. We develop model practices not as a means of judging or evaluating programs, but rather as a means of sharing those practices that have proven successful for one State so that other States may determine the merit of adopting similar practices in their own SCHIP implementation.

Comment: One commenter recommended that we require States to report on the provision of services as well as the participation rates of pediatricians and other child health care providers in the program. Additionally, the commenter recommended that we require States to report the average cost-sharing requirements for families who choose to enroll in SCHIP rather than employer-provided coverage. The commenter believed that we should also require States to include an evaluation of the impact States' efforts to minimize substitution have had on children with special health care needs and their access to services. The commenter believed that HCFA should also require States to include evaluations of their screen and enroll processes.

Response: We do not agree with the commenter's suggestion. The evaluation template developed by the National Academy for State Health Policy reflects those elements specified in section 2108(b)(1)(B) of the Act. To this extent, it did include assessment questions on the State's cost sharing and its effects on participants as well as questions regarding the State's screen and enroll process and its substitution policies and results of monitoring rates of substitution. We have further included a provision at § 457.353 that specifically requires States to monitor and evaluate the effectiveness of the screening process. The regulatory requirements are consistent with the statute. In some cases, States included additional data or other information such as the data suggested by the commenter, in their SCHIP evaluations as additional measures of their progress toward strategic objectives of that State.

Comment: One commenter supported the proposed categories of evaluation, but requesting that we require more frequent reporting and evaluation.

Response: Section 2108(b) of the Act, as implemented in § 457.760, required States to submit evaluations by March 31, 2000. We believe the information States will be providing through the quarterly and annual reports required by § 457.740 and § 457.750 respectively, will be sufficient to allow ongoing assessments of States' SCHIP programs, making more frequent reporting and formal evaluations unnecessary and overly burdensome on States. The statute did not include a subsequent requirement for an annual evaluation and we have, therefore, removed this provision from the final rule.

Comment: One commenter recommended that HCFA clarify § 457.750(c)(1) by replacing the phrase ''coverage by other health insurance prior to the State plan'' with ''coverage by other health insurance prior to coverage under the State plan.''

Response: Because we have deleted this provision from the final rule, we have not adopted the commenter's suggestion.

Comment: One commenter recommended that HCFA encourage States to build on existing data collection efforts and systems, including State title V efforts, in developing overall SCHIP evaluation efforts and in collection of data.

Response: We encourage States to build on existing databases and title V efforts, as well as public-private partnerships in order to facilitate the development and implementation of information tracking systems and SCHIP program evaluation efforts.

G. Subpart H—Substitution of Coverage

1. Basis, Scope, and Applicability (§ 457.800)

Title XXI requires that States ensure that coverage provided under SCHIP does not substitute for coverage under either private group health plans or Medicaid. Section 2102(b)(3)(C) of the Act requires that State plans include descriptions of procedures used to ensure that the insurance provided under the State child health plan does not substitute for coverage under group health plans. Another provision in title XXI relating to substitution of coverage is section 2105(c)(3)(B), which sets out the conditions for a waiver for the purchase of family coverage as described in § 457.1010. Under this provision, States must establish that family coverage would not be provided if it would substitute for other health insurance provided to children.

In addition, title XXI contains several provisions aimed at preventing SCHIP from substituting for current Medicaid coverage. First, sections 2102(a)(2) and 2102(c)(2) of the Act requires States to describe procedures used to coordinate their SCHIP programs with other public and private programs. Second, section 2105(d) of the Act includes ''maintenance of effort'' provisions for Medicaid eligibility. That is, under section 2105(d) of the Act, a State that chooses to create a separate child health program cannot adopt income and resource methodologies for Medicaid children that are more restrictive than those in effect on June 1, 1997. Furthermore, section 1905(u)(2)(b) of the Act also provides that a State that chooses to create a Medicaid expansion program is not eligible for enhanced matching for a separate coverage provided to children who would have been eligible for Medicaid in the State under the Medicaid standards in effect on March 31, 1997. Finally, section 2102(b)(3)(B) of the Act requires that any child who applies for a separate child health program must be screened for Medicaid eligibility and, if found eligible, enrolled in Medicaid.

This subpart interprets and implements section 2102(b)(3)(C) of the Act regarding substitution of coverage

under group health plans and sets forth State plan requirements relating to substitution of coverage in general and specific requirements relating to substitution of coverage under premium assistance programs. These requirements apply only to separate child health programs.

Comment: Many commenters questioned the magnitude of the risk for substitution of private group health plan coverage by SCHIP coverage for children. Because the size of the risk of substitution by SCHIP coverage offered under both employer-sponsored insurance programs and non-employer-sponsored insurance programs is unclear, and because of the harm that substitution prevention policies may inflict, the commenters encouraged HCFA not to put forth a policy to prevent substitution that goes beyond what is clearly required by the statute. Many commenters also recommended that we revisit our policy on substitution because of their concern that waiting periods and other substitution prevention policies are causing significant harm to families with children with special health care needs and argued that such families can ill afford to go without coverage for any period of time.

Response: We have revisited our policy on substitution and made several changes. With respect to substitution policies outside of the context of premium assistance programs, we note that the proposed regulatory text at § 457.805 requires only that the State plan include reasonable procedures to prevent substitution. This approach permits State flexibility and implementation of policies based on the emerging research regarding substitution and on State experiences with substitution.

Our review of States' March 31, 2000 evaluations indicated that in those States with data on substitution of private coverage with SCHIP coverage, there was little evidence that substitution was as great an issue as initially anticipated.

Thus, we have revised the policy stated in the preamble to the NPRM regarding substitution procedures relating to SCHIP coverage provided outside of programs that offer premium assistance for coverage under group health plans as follows: States that provide coverage to children in families with incomes at or below 200 percent of FPL must have procedures to monitor the extent of substitution of SCHIP coverage for existing private group health coverage, as was the policy for such coverage provided to families under 150 percent of FPL proposed in the preamble to the NPRM.

States that provide coverage to children in families with incomes over 200 percent of FPL should, at a minimum, have procedures to evaluate the incidence of substitution of SCHIP coverage for existing private group health coverage. In addition, States offering coverage to children in families over 200 percent of FPL must identify in their State plans specific strategies to limit substitution if monitoring efforts show unacceptable levels of substitution. States must determine a specific trigger point at which a substitution prevention mechanism would be instituted, as described in the State plan. For coverage above 250 percent of the FPL, because evidence shows that there is a greater likelihood of substitution at higher income levels, States must have substitution prevention strategies in place, in addition to monitoring.

Although a period of uninsurance is one possible substitution prevention procedure, we invite States to propose other effective strategies to limit substitution. States may submit amendments to their State plans if they would like to modify their current policies in light of the policies discussed here. We plan to work closely with each State to develop appropriate substitution strategies, monitoring tools, and trigger mechanisms.

For premium assistance programs, we have revised our substitution policy in this final rule in two areas. We have eliminated the requirement for a 60 percent minimum employer contribution. We will no longer mandate a specific level of contribution, since a substantial employer contribution must be made in order for coverage subsidized through employer plans to be cost-effective, as required under § 457.810. States will be expected to identify a reasonable minimum employer contribution level and provide justification for that level, including data and other supporting evidence, that will be reviewed in the context of the State plan amendment process. In addition, as proposed in the NPRM, States with premium assistance programs must monitor employer contribution levels over time to determine whether substitution is occurring and report their findings in their State annual reports.

The identification of the minimum employer contribution and the monitoring process will help ensure that SCHIP funds are being used to supplement the cost of employer-sponsored insurance, not supplant the employers' share of the cost of coverage. While these revisions are intended to provide additional State flexibility to develop premium assistance programs and provide coverage to families, it is important to note that the cost-effectiveness test established by title XXI and set forth in § 457.810 must be met in all cases.

The second change we are making relates to the required waiting period of uninsurance. We have retained the requirement for a minimum 6-month period without group health coverage, but will permit exceptions to the waiting period, as discussed in more detail in the comments and responses to section § 457.810.

2. State Plan Requirements: Private Coverage Substitution (§ 457.805)

The potential for substitution of SCHIP coverage for private group health plan coverage exists because SCHIP coverage may cost less or provide better coverage than coverage some individuals and employers purchase with their own funds. Specifically, employers who make contributions to coverage for dependents of lower-wage employees could potentially save money if they reduced or eliminated their contributions for such coverage and encouraged their employees to enroll their children in SCHIP. At the same time, families that make significant contributions towards dependent group health plan coverage could have an incentive to drop that coverage and enroll their children in SCHIP if the benefits would be comparable, or better, and their out-of-pocket costs would be reduced.

In accordance with section 2102(b)(3)(C) of the Act, we proposed at § 457.805 to require that each State plan include a description of reasonable procedures that the State will use to ensure that coverage under the State plan does not substitute for coverage under group health plans.

We opted not to propose specific procedures to limit substitution. Instead, we discussed in detail reasonable procedures that States may use to prevent substitution of coverage. Specifically, we stated in the preamble to the NPRM that we would consider the following to be reasonable procedures for addressing the potential for substitution:

- States that provide coverage to children in families at or below 150 percent of the Federal poverty line (FPL) should, at a minimum, have procedures to monitor the extent of substitution of that coverage for existing private group health coverage.
- States that provide coverage to children in families between 150 and

200 percent of FPL should, at a minimum, have procedures to study the incidence of substitution of that coverage for existing private group health coverage. In addition, States should specify in their State plans the steps they will take to prevent substitution in the event that the States' monitoring efforts discover substitution has occurred at an unacceptable level.

• States that provide coverage to children in families above 200% of FPL should implement, concurrent with program implementation, specific procedures or a strategy to limit substitution.

We noted that we would ask States to assess the procedures to limit substitution in their evaluations submitted in March of 2000. We also asked all States that specified in their plans that they would monitor substitution to submit information on substitution in their annual reports.

We also addressed the issue of applying substitution provisions to the Medicaid eligibility group for the ''optional targeted low-income children'', which was added to section 1902(a)(10)(A)(ii)(XIV) of the Act pursuant to section 4911 of the BBA. In the NPRM we clarified that States may not apply eligibility-related substitution provisions, such as periods of uninsurance, to the ''optional targeted low-income children'' group, because such eligibility conditions are inconsistent with the entitlement nature of Medicaid. We have retained this policy in this final regulation. States that currently apply eligibility-related substitution provisions to optional targeted low-income children will need to come into compliance with this clarified policy. States that have not already come into conformity with this policy will have 90 days from the date of this notice to do so and must submit a State plan amendment in compliance with § 457.65(a)(2). We recognize that States expanding Medicaid to optional targeted low-income children at higher income levels may be particularly concerned about the potential for substitution of coverage. States that want to maintain waiting periods for the optional targeted low-income children group may want to submit section 1115 demonstration requests for approval of substitution provisions. HCFA will consider section 1115 demonstration requests on a case-by-case basis.

Comment: Although neither the preamble nor the proposed regulatory text explicitly prescribed a mandatory waiting period or period without group health insurance, as a condition of eligibility in separate child health programs that are not providing premium assistance for group health plans, many commenters expressed their dislike for the Department's policy implemented in the course of approving State plans and plan amendments, of mandating the imposition of periods without insurance for populations over 200 percent of the FPL.

Many commenters indicated that waiting periods are unnecessary in general because they block access to care without any proof of their effectiveness in preventing substitution. Some commenters stated that the data on the significance of substitution has been inconclusive. One commenter referred to recent data from the Current Population Survey (CPS) on trends in coverage for low-income children that, in their view, raised serious questions about the magnitude of any crowd out effect of expansions in publicly-funded coverage for children. Another concern raised was that waiting periods without insurance impose a significant hardship for families who may be struggling to keep up premium payments, obtain care for children with special health care needs, or get by with inadequate private coverage for their children.

Response: Our review of States' March 31, 2000 evaluations indicated that in those States with data on substitution of private coverage with SCHIP coverage, there was little evidence that substitution was as great an issue as initially anticipated. However, because of the current lack of conclusive data around the level of substitution which may be occurring below 200 percent of FPL, we maintain that monitoring of substitution of coverage in SCHIP is critical.

As noted above, we have revised the policy stated in the preamble to the NPRM regarding substitution procedures relating to SCHIP coverage provided outside of programs that offer premium assistance for coverage under group health plans as follows:

• States that provide coverage to children in families at or below 200 percent of FPL must have procedures to monitor the extent of substitution of SCHIP coverage for existing private group health coverage, as was the policy for such coverage provided to families under 150 percent of FPL proposed in the preamble to the NPRM.

• At a minimum, States that provide coverage to children in families with incomes over 200 percent of FPL should have procedures to evaluate the incidence of substitution of SCHIP coverage for existing private group health coverage. In addition, States offering coverage to children in families over 200 percent of FPL must identify in their State plans specific strategies to limit substitution if monitoring efforts show unacceptable levels of substitution. States must monitor the occurrence of substitution and determine a specific trigger point at which a substitution prevention mechanism would be instituted, as described in the State plan.

• For coverage above 250 percent of the FPL, because evidence shows that there is a greater likelihood of substitution at higher income levels, States must have substitution prevention strategies in place, in addition to monitoring.

Although a period of uninsurance is one possible substitution prevention procedure, we invite States to propose other effective strategies to limit substitution. States may submit amendments to their State plans if they would like to modify their current policies in light of the policies discussed here. We plan to work closely with States to develop appropriate substitution strategies, monitoring tools, and trigger mechanisms. As part of monitoring for substitution of coverage, States should also study the extent to which anti-substitution policies require children who have lost group health coverage through no fault of their own or their employer to wait to be enrolled in SCHIP. To the extent that monitoring finds that such children are forced to go without coverage, States should consider adjustments to their substitution prevention policies that permit exceptions for children who should not be the target of such policies. We will continue to ask States to assess their substitution prevention procedures in their annual reports.

Finally, we note that because the regulatory text at § 457.805 required that the State plan include reasonable procedures to prevent substitution and made no distinction for eligibility levels for coverage under State plans, we have not revised the regulation text. It is consistent with our revised policy.

Comment: Several commenters believed that States should be allowed to establish guidelines that would allow families to drop coverage without penalty of a SCHIP-required waiting period and to enroll the child or children in the State's SCHIP program if they are paying more than they can afford for the child's insurance. The commenters indicated that, in some cases, the child may have special health needs and/or the family may be paying for insurance that does not cover many of the child's needs but serves only as insurance against a catastrophic event. In addition, some commenters suggested that States not be allowed to impose periods of uninsurance that impede the

delivery of preventive care and immunizations consistent with the AAP Guidelines for Health Supervision III and Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents.

Response: As stated above, periods of uninsurance will not be required unless coverage is provided via premium assistance through group health plans, coverage is provided to children with significantly higher income levels, or substitution has been identified as a problem in the State. Furthermore, in the case of States with premium assistance programs, we continue to permit States to cover such children under a separate child health program (outside of coverage through premium assistance programs) during the waiting period, as stated in the preamble to the proposed rule. The required period of uninsurance applies only to SCHIP coverage provided through group health plans.

States are therefore able to enroll special needs children, and those in need of preventive care and immunizations, in SCHIP in a timely fashion so as not to disrupt the provision of needed health care services. To the extent a State chooses to adopt periods of uninsurance, the State may want to consider exceptions to the period of uninsurance to address issues raised by the commenters. We note, however, that access to immunizations is unlikely to be proposed as an exception since virtually all younger children would thereby be exempt.

Comment: One commenter urged the Department to view State substitution prevention efforts as a comprehensive plan, rather than isolating specific pieces that may or may not measure up to artificial Federal guidelines. In addition, the commenter noted that each State has developed a substitution prevention strategy that is applicable to the demographic and economic situation in the State, and State plans should therefore be judged in their entirety, not in a piecemeal fashion.

Response: We agree that State's substitution prevention efforts should be considered in the context of the entire State plan with consideration given to a State's particular needs and goals. To this end, we have retained a flexible regulatory requirement regarding substitution and indicated that HCFA will incorporate additional flexibility in its plan review process.

Comment: One commenter agreed with the language in proposed § 457.805 and suggests that HCFA limit States' discretion to use fears about substitution as an excuse to deny health coverage and recommended that final regulations bar waiting periods (outside of the premium assistance arena) that either: (1) Impose harm on children by going beyond 6 months or deny coverage (except where the employee voluntarily drops employment-based coverage without any change in circumstances) for pregnant women, children with disabilities, or children with preexisting conditions as defined by HIPAA; or (2) deny SCHIP benefits to children without employer-sponsored insurance for reasons unrelated to SCHIP (recent adoption, loss of job, end of COBRA coverage, death of a parent, moving outside the plan's service area, or an increase in premiums that was unaffordable to the family).

Response: As indicated above, outside of premium assistance programs, States have broad discretion to develop substitution prevention policies that best serve their particular populations. States that choose to retain or impose periods of uninsurance are encouraged to include exceptions that help prevent the imposition of undue hardship under a range of circumstances, including loss of insurance through no fault of the family, extreme economic hardship, death of a parent, etc.

Comment: One commenter indicated that, while in agreement that our proposed policy on substitution for the lower income population is reasonable, HCFA should carefully monitor State programs for children under 200% FPL to assure that no substitution problems emerge.

Response: We will continue to review State plan amendments to ensure that States monitor the occurrence of substitution at all income levels, and to review annual reports for any reported experiences of substitution. As stated in previous guidance from HCFA, in the event monitoring efforts indicate unacceptable levels of substitution, HCFA may reconsider the requirements intended to prevent substitution of coverage.

Comment: One commenter indicated confusion about the preamble language which ''does not require'' the use of eligibility-related substitution prevention provisions such as periods of uninsurance for the Medicaid eligibility group for the ''optional targeted low income children,'' but goes on to say that States that currently apply eligibility-related substitution prevention provisions to optional targeted low-income children ''will need to come into compliance with this proposed policy.'' The commenter believed our language should have indicated we would ''not allow'' such States to impose a waiting period as opposed to ''not require.''

Response: The commenter is correct. The policy is that the Medicaid statute does *not allow* the use of eligibility-related substitution prevention provisions such as periods without insurance for ''optional targeted low income children'' (outside of demonstration projects under the authority of section 1115 of the Act).

Comment: One commenter asked for clarification whether the proposed requirements with respect to substitution at § 457.800(c) applied only to separate child health programs and not to Medicaid expansion programs.

Response: As noted by the commenter, this point needs clarification. This subpart, as stated at § 457.800(c), applies only to separate child health programs. We have removed the reference to subpart H at § 457.70, which had indicated the requirements that apply to Medicaid expansion programs.

Comment: Several commenters indicated support for the clarification that waiting periods are not allowed in Medicaid expansions (outside of section 1115 demonstrations). One commenter asserted that this is consistent with Congressional intent that all Medicaid rules should apply to title XXI expansions of Medicaid. Another commenter suggested using caution when granting 1115 demonstrations to implement substitution prevention provisions when expanding Medicaid eligibility.

Response: We agree with the first two points and note the concerns raised in connection with section 1115 demonstrations.

Comment: One commenter indicated that States should be permitted the flexibility to implement the substitution provisions that they determine are necessary for their own SCHIP programs, and that this should be the rule whether the program is a Medicaid expansion or a separate program. Another commenter believed that it is unfair not to require a six-month waiting period for Medicaid expansion programs because it presents an unfair barrier to separate child health programs.

Response: The final rule allows States the flexibility to identify and implement substitution prevention provisions that are necessary for their own separate child health programs, within the parameters discussed above. Title XXI explicitly requires States to have substitution policies. By contrast, waiting periods are not permitted in Medicaid expansion programs outside of section 1115 demonstrations.

Comment: One commenter stated that HCFA should consider whether the imposition of substitution provisions, such as mandated periods of uninsurance applied to adults under family coverage waivers, would have an undesirable effect on the children's access to services.

Response: We agree that waiting periods may have an adverse impact on children's access to care. In this final rule, HCFA is requiring States to monitor the extent to which substitution prevention policies require children who have lost group health coverage, through no fault of their own or on the part of their employer, to wait to be enrolled in SCHIP. If monitoring shows that such children are forced to go without coverage, States should consider adjustments to their substitution prevention policies that permit exceptions for children who should not be the target of such policies. Because research shows that the risk of substitution is greater when a State operates a premium assistance programs, we will continue to require that such coverage be available after a six month period of uninsurance. However, this policy does not prevent States from covering SCHIP enrollees, whether children or families, through a separate child health program or through Medicaid. The final rule also permits States to adopt reasonable exceptions to the waiting period requirement. (See the discussion of the comments and responses on § 457.810.) Thus, the premium assistance substitution policy does not require that children be uninsured prior to enrolling in a premium assistance program.

Comment: One commenter believed that collaboration with the Child Support Enforcement Program is necessary and that any efforts to monitor potential substitution of private employer group coverage should include a review for coverage which may already be provided by a noncustodial parent, or which may potentially be available through a noncustodial parent pursuant to a support order. The commenter also asked that the definition of substitution be clarified and recommended a definition of ''equivalent to SCHIP coverage'' or some State-defined minimum requirements. The commenter appeared to believe that coverage inferior to SCHIP coverage carried by a noncustodial parent should not be considered health insurance coverage when determining whether SCHIP coverage is substituting for private group health insurance coverage.

Response: We agree that a State's SCHIP program should coordinate with the State's Child Support Program and that coverage under, or available through, a noncustodial parent's health plan should be considered by the State with respect to its substitution policies. The commenter is concerned that coverage available from the noncustodial parent be equal to SCHIP coverage or some State-defined minimum coverage before a concern for substitution should arise. We note that this final rule does not require that children be denied SCHIP coverage if the noncustodial parent has insurance that could cover the child. CSE agencies should be informed about the availability of SCHIP coverage because, as the commenter suggests, SCHIP coverage might provide better access to care than coverage potentially available through the noncustodial parent. The statutory provisions do, however, preclude SCHIP eligibility for a child who already has coverage under a group health plan or health insurance coverage, as those terms are defined under HIPAA. The only exceptions to this policy are if the child does not have ''reasonable geographic access'' to coverage, as described in subpart C, or if the policy meets the definition of ''excepted benefits'' under HIPAA.

3. Premium Assistance Programs: Required Protections Against Substitution (§ 457.810)

We proposed under § 457.810 to require any State that implements a separate child health program under which the State provides premium assistance for group health plan coverage, to adopt specific protections against substitution. A State must describe these protections in the State plan. In the NPRM, we proposed that the following four requirements would need to be met to protect against substitution:

• *Minimum period without group health plan coverage.* The child must not have been covered by a group health plan during a period of at least six months prior to application for SCHIP. States may require a child to have been without such insurance for a longer period, but that period may not exceed 12 months. States may permit exceptions to the minimum period without insurance if the prior coverage was involuntarily terminated. We noted that newborns who are not covered by dependent coverage would not be subject to a waiting period. We also noted that the waiting period applies only to coverage through a group health plan, not SCHIP or Medicaid coverage. If an otherwise eligible child does not meet the requirement for a minimum period without group health plan coverage, the State can enroll the child in SCHIP under a separate child health program without purchasing employer-sponsored coverage for the interim waiting period, and can still consider the child uninsured for purposes of the waiting period. That is, coverage under a separate child health program or Medicaid does not count as group health insurance coverage for purposes of the required waiting period prior to enrollment in SCHIP coverage provided via premium assistance programs.

• *Employer contribution.* The employer must make a substantial contribution to the cost of family coverage, equal to 60 percent of the total cost of family coverage. States proposing a minimum employer contribution rate below this standard must provide the Department with data that demonstrate a lower average employer contribution in their State and support a State's contention that the lower contribution level will be equally effective in ensuring maintenance of statewide levels of employer contribution. In addition, the employee must apply for the full premium contribution available from the employer.

• *Cost-effectiveness.* The State's payment under its premium assistance program must not be greater than the payment that the State otherwise would make on the child's behalf for other coverage under the State's SCHIP program.

• *State evaluation.* The State must collect information and evaluate the amount of substitution that occurs as a result of payments for group health plan coverage and the effect of those payments on access to coverage. To conduct this evaluation, States must assess the prior insurance coverage of enrolled children. States may obtain information on prior coverage through the enrollment process, separate studies of SCHIP enrollees, or other means for reliably gathering information about prior health insurance status. In the preamble to the NPRM, we set forth specific examples of questions States could include in SCHIP applications to evaluate the prevalence of substitution. We noted that we would reevaluate our position on the requirements for States that subsidize employer-sponsored plans based on our review of the State evaluations due March 31, 2000.

Comment: One commenter noted that employer ignorance of changing public benefit rules is one of the most effective safeguards against widespread substitution, and things such as competitive market pressures and rising health costs, not changing Medicaid and SCHIP coverage rules, drive reductions in employer subsidies for health

coverage. Further, the commenter stated that the safeguard of employer ignorance ends when the employer is contacted by a State agency and becomes a partner in purchasing SCHIP coverage. Another commenter indicated their belief that HCFA is inconsistent by indicating that it will scrutinize SCHIP programs subsidizing employer-sponsored insurance while suggesting (in § 457.90) that ''Employer-based outreach is another avenue for providing * * * information on children's insurance programs.''

Response: We note these comments and have sought to craft a substitution prevention policy that reflects the different pressures on the employer market and that balances States' desire for developing premium assistance programs with the risk that such programs will not expand coverage for children, but merely substitute employer contributions with SCHIP funds. There are both benefits and risks of partnering with employers in designing premium assistance programs. We have provided new flexibility to States to design such programs under these final rules, while retaining some requirements that are critical for preventing substitution.

Comment: Many commenters indicated their strong disagreement with the mandatory six-month minimum period without group health insurance coverage prior to application for SCHIP premium assistance coverage through group health plans. Their arguments against this policy included that it has no basis in statute, that it is inconsistent with other SCHIP strategies to prevent substitution which allow State flexibility, and that waiting periods block access to coverage and care for an arbitrary period without evidence of the effectiveness of any particular length of waiting period in preventing substitution. Some of these commenters added that if HCFA maintains a requirement for a period without employer-sponsored insurance prior to eligibility for SCHIP coverage obtained through premium assistance programs, that the minimum period be changed to 3 months. One commenter noted that there is no State system in place to confirm if and when an individual was previously covered under group health plans and that requiring States to establish such a system would be onerous and administratively costly.

Response: We have revisited and made revisions to our policy on substitution generally, and our policy on required periods of uninsurance, with respect to premium assistance for coverage under group health plans.

As discussed above, when a State operates premium assistance for group health insurance coverage, the State is no longer required to comply with the requirement that the employer contribution be at least 60 percent of the premium cost. The other requirements described in the proposed rule would continue to apply; namely, the requirements that the employee eligible for the coverage apply for the full premium contribution available from the employer, that such coverage be cost-effective, and that the State evaluate the amount of substitution that occurs as a result of payments for group health insurance coverage and the effect of those payments on access to coverage.

In addition, because of the greater likelihood of substitution of SCHIP coverage for group health insurance coverage offered by employers, we are retaining the requirement for a 6-month waiting period, but allowing States greater flexibility to vary from this general requirement. The default substitution prevention mechanism will be a period of uninsurance of at least six months, and not more than 12 months, without group health insurance prior to eligibility for SCHIP premium assistance for coverage through group health insurance plans offered by employers. States may also develop reasonable exceptions to the required waiting period when they can identify limited circumstances in which substitution is less likely to occur. For example, if a State is targeting its premium assistance program to certain employers that provide only very limited health insurance coverage, a waiting period may not necessarily be required since the likelihood of substitution would be limited in those circumstances.

In proposing exceptions to the six-month waiting period, States must provide reasonable justification for such exceptions, including data and other supporting evidence, as appropriate, which will be reviewed by HCFA in the context of the State plan amendment process. We have also listed several specific exceptions to the waiting period that may be granted, including involuntary loss of coverage due to employer termination of coverage for all employees and dependents, economic hardship, and change to employment that does not offer dependent coverage. And, as noted above, States also must monitor their premium assistance programs to determine whether substitution may be occurring. We plan to work closely with States interested in providing coverage via premium assistance for group health insurance coverage in order to provide technical assistance and help achieve a balanced approach that allows premium assistance plans to be implemented with appropriate safeguards to prevent substitution.

Comment: Many commenters expressed concern about the 60 percent employer contribution requirement at proposed § 457.810(b)(2) for SCHIP coverage provided through employer-sponsored insurance because employer contributions may vary in a State based on region, type and size of business, and wage levels of employees. The commenters' expressed the position that HCFA has exceeded its statutory authority in setting this benchmark, and they argued that it is unnecessary. Furthermore, the commenters stated that few employers contributing less than 60 percent of the premium would meet the required cost effectiveness test. The commenters noted that the statutory requirement that the purchase of employer-sponsored insurance with SCHIP funds must be cost effective is the most appropriate tool to use. One commenter indicated that the employer contribution standard should not be based on a statewide average of all businesses, but should be appropriate to, and specific to, those businesses which would participate in the SCHIP program that would utilize an existing health purchasing cooperative consisting of small businesses. One commenter also indicated that the level of substitution is unlikely to be affected by the 60 percent requirement, because employers would probably not base their health coverage decisions on the needs of employees eligible for premium assistance who, for many companies, represent only a small fraction of their overall employee pool. The commenter stated that crowd out occurs because of individual rather than corporate decisions, such as when individual employees elect to drop private coverage for low-cost or no-cost public assistance. Finally, the 60 percent would be problematic for some commenters' States because those States are operating under approved 1115 demonstrations to allow premium assistance when employers contribute at least half the cost of coverage.

Another commenter cited a survey that showed that in regions other than on the east coast, very few employers pay any part of the dependent premium. The recent survey indicated on average, large employers pay 85.51% of the employee premium and 17.62% of the dependent premium, and that small employers contribute 78.06% of the employee premium and 5.14% of the dependent premium. According to this commenter, HCFA's requirement

actually prevents access for many children.

Several commenters that disagreed with the 60 percent employer contribution requirement suggested it be deleted in favor of maintaining a cost-effectiveness test while requiring States to simply describe how they plan to monitor employer contribution percentages to detect any reductions in the contributions and assess whether reductions may be related to SCHIP premium assistance. Other commenters also recommended subjecting employers to a maintenance of effort requirement with respect to the contribution level.

One commenter recommended that if a minimum requirement is maintained, States be permitted to establish different standards for different kinds of employers, including making distinctions based on whether or not the employer has previously offered health insurance coverage and on the wage distribution of the employer's work force.

It was one commenter's opinion that failure to allow State flexibility on the employer contribution will stifle many potential innovative approaches to reach uninsured children of low-wage workers and that States will be unable to enroll sufficient numbers of children in these programs to justify the administrative expense. In addition, in this commenter's view, the 60 percent requirement may result in many families who would prefer premium assistance being forced to enroll their children in the regular SCHIP program, and force the State to forego any employer contribution. The commenter also noted that, if more low-wage workers decline dependent coverage when it is offered, employers with many low-wage workers may stop offering coverage, causing a long-term, population-wide shift from private to public sources of coverage.

Another commenter stated that the small employers in its State do not pay 60 percent of family health coverage premiums and, in fact, most do not cover dependents. The commenter believed that they should be allowed to include in premium assistance programs employers who are currently not covering dependents. They suggested a rule that would only include employers who did not cover dependents as of a certain date, or who paid less than a predetermined amount for coverage as of that date. The State would then use local objective data (and not ''outdated, national surveys of large employers'') to determine the contribution amount appropriate for the locality. One commenter indicated that our proposed policy would punish families who find jobs with employers who contribute less than 60 percent and encourage them to take jobs with employers that don't offer family coverage.

A commenter also suggested that whatever standard is adopted, there should be exceptions in instances in which employer contribution percentages drop solely because of an increase in premiums or where an employer drops its level of contribution because of documented and significant economic declines. In such cases, the commenter argued, crowd out isn't a factor in the reduced employer contribution level, and failure to allow employers in such circumstances to reduce their contribution levels may result in employees and their families losing their insurance. One commenter said, regarding the 60 percent employer contribution, that HCFA should not presume the cost neutrality of State initiatives to link title XIX/XXI coverage to low-wage workers, and said that the proposed regulations indirectly restrict a State's discretion to define eligibility and thereby exceed Congressional intent. Moreover, in this commenter's view, by establishing such a high level of employer contribution, HCFA effectively is excluding dependents of small business employees from participating in SCHIP.

Another commenter stated that a required percentage of employer contribution for participation in SCHIP premium assistance programs would give employers a target that could be misused. If an employer arbitrarily reduced its percentage of contribution, the employer could eliminate the opportunity for additional SCHIP-eligible employees to purchase employer health insurance with the help of premium assistance. In the commenter's State, only 2.5 percent of eligible individuals with access to employer-sponsored health coverage have access to family coverage where the employer pays 60 percent or more of the premiums. For nearly 30 percent of the State's eligibles with access to family coverage via an employer, the employer contributes about 10 percent less than the 60 percent minimum. In this commenter's view, our proposed rule would eliminate the opportunity for these individuals to be covered under a premium assistance program.

One commenter expressed disappointment that HCFA did not deviate from the policy expressed in the February 13, 1998 letter and indicated that the guidance is overly prescriptive and biased against the development of State approaches to SCHIP using employer-sponsored coverage. The commenter suggested providing additional State flexibility in determining the amount of employer contribution as long as plans certify that issues related to crowd out and substitution are addressed. If, upon evaluation, State efforts do not result in permissibly low levels of substitution, the commenter stated they would be happy to assist in the development of more detailed and specific guidelines. If the 60 percent requirement is not eliminated, this commenter suggested that States should be allowed to develop an alternative State average based on size of business, number of employees, number of low-wage employees or some other relevant factor.

Another commenter stated that there is no evidence in its Health Insurance Premium Program (HIPP) that employers have reduced their contribution because HIPP is paying the premium, and the commenter would not expect employers to act differently with respect to SCHIP. The commenter indicated that employers have other employees to consider and there is no evidence to support the position that employers will reduce their contribution because some employees are subsidized. They stated their belief that the majority of employers recognize the value of providing health care coverage to their employees and want them insured.

In this commenter's view, HCFA's position penalizes employees of employers who are not financially able or willing to contribute more, especially when health plans impose large premium increases. Also, the commenter believed that HCFA's position penalizes States by limiting their ability to buy-in to cost effective employer coverage and increasing the administrative burden for States. The commenter recommended that, if the employer plan is cost effective, States should have the flexibility to take advantage of the coverage, regardless of the amount of employer contribution.

Response: We appreciate the concerns raised by these commenters and we have revised our policy in this final rule to provide additional flexibility for States wishing to utilize premium assistance programs. We will no longer require States to implement a minimum employer contribution of 60 percent. We agree with the commenters' position that the cost-effectiveness requirement of the statute reduces the need for a uniform minimum employer contribution level, because it is likely that a substantial employer contribution would be necessary in order to meet the test of cost-effectiveness. However, States must identify a specific minimum employer contribution level to ensure

that SCHIP funds are used to supplement the cost of employer-sponsored insurance rather than supplant the employers' share of the cost of coverage, and we have maintained the requirement that States evaluate substitution in the context of their premium assistance program in their annual reports. While allowing for significant new flexibility, this policy also encourages States to require the highest possible employer contribution level that is reasonable given the circumstances in their State. In addition, the rules maintain the requirement that the employee eligible for the coverage must utilize the full premium contribution available from the employer.

We recognize that it may be necessary to revisit this policy as States gain experience with the provision of SCHIP coverage and we receive further evaluations of substitution with respect to SCHIP coverage provided through premium assistance for employer-sponsored insurance. The requirements set forth in this final rule represent our position on the steps necessary to implement the statutory provisions of section 2102(b)(3)(c) of the Act in light of what is now known about the interaction between private and public coverage. The rules provide considerable flexibility, allowing States and HCFA room to adjust the approach to substituion based on experience with the program.

Comment: One commenter agreed with the proposed rule's flexibility to allow less than 60 percent employer contribution to family coverage if the State average is less than 60 percent.

Response: We appreciate the support and as stated above, we have dropped the 60 percent contribution requirement in part because we recognize the variation in levels of average employer contributions across States.

Comment: One commenter strongly disagreed with our proposal to allow States to set a lower standard for employer contributions than 60 percent. The commenter asserts that because of the lack of data on ''average'' employer contributions to dependent coverage, especially with regard to small employers, and the fact that the average contribution among employers with 50 or fewer employees is zero percent, and in the commenter's State large employers also often contribute nothing, the commenter believes our proposed policy of allowing a less than 60 percent contribution would permit the allowance of premium assistance programs even where the employer contributes nothing at all.

Response: A contribution level of less than 60 percent is permitted under these final rules, as long as the cost-effectiveness test is met. We do not agree that premium assistance programs likely would be allowed when there is no employer contribution, as the commenter suggested, because the cost-effectiveness test is unlikely to be met without a substantial employer contribution.

Comment: One commenter suggested that HCFA clarify whether (and how) the NPRM's preamble discussion of determining cost-effectiveness under family coverage waivers applies with respect to using employer-sponsored insurance to provide coverage under SCHIP.

Response: The cost-effectiveness requirement in § 457.810(c) applies when a State provides premium assistance programs for SCHIP eligible children. The cost-effectiveness test for premium assistance for group health insurance coverage requires a comparison of the cost of coverage of the child that would otherwise be available under SCHIP to the State's cost to provide premium assistance for group health insurance coverage for that child. We have modeled the discussion of the cost-effectiveness test in the regulation text after the provision related to States that wish to cover family members, in addition to targeted low-income children at § 457.1015. We have specified that the State's cost for coverage for children under premium assistance programs must not be greater than the cost of other SCHIP coverage for these children. Consistent with cost-effectiveness test for family coverage, the State may base its demonstration of cost-effectiveness on an assessment of the cost of coverage for children under premium assistance programs to the cost of other SCHIP coverage for these children, done on a case-by-case basis, or on the cost of premium assisted coverage in the aggregate.

See the discussion at § 457.1015 for further details on cost-effectiveness for family coverage waivers.

Comment: One commenter indicated that the 60 percent requirement would unrealistically require a large base of employers to report data on contribution levels to the State in order for the State to satisfy the contribution requirement. Other commenters suggested we require States to evaluate the percent of income families would have had to spend to maintain employment-based or individual coverage during the period they waited for SCHIP coverage in assessing their substitution prevention procedures for their March 2000 evaluations and annual reports. They recommended that State evaluations and annual reports assess whether individual employers are terminating coverage for low-wage workers while maintaining coverage of higher wage workers and executives. Such an assessment should also examine increases in the amounts that employers are asking low-wage workers to contribute toward employment-based insurance coverage. Another commenter noted that few States will have implemented the employer buy-in option by the time of the March 2000 evaluations for HCFA to establish policy based on those evaluations.

Response: We are no longer imposing a minimum employer contribution requirement and recognize that there is not much experience to-date with premium assistance programs. As HCFA and the States gain experience, we will be in a better position to evaluate the extent of substitution taking place. We recognize that there is limited data regarding employer coverage and contributions based on wage-levels of employees as well as State based information on the percent of income families would have had to spend to maintain private coverage while waiting for SCHIP coverage. In addition, we note that market forces other than SCHIP may influence the level of employer contribution and further complicate such analyses. We encourage States to assess these issues but recognize that data to support such assessments may be difficult to obtain and therefore do not require it.

Comment: Several commenters noted concern about HCFA's policy permitting States to provide direct SCHIP coverage to children during the six-month waiting period via the State's separate child health program (other than premium assistance programs). Commenters indicated that this policy itself would actually facilitate crowd out as families dropped their privately-funded coverage in favor of publicly-funded benefits and that the privately-funded coverage would not resume until six months of publicly-funded coverage passed. In addition, one commenter noted that coverage under the State's regular SCHIP program is less cost-effective than its coverage under a premium assistance program.

Response: To the extent that the part of State's separate child health program that does not involve premium assistance requires either no period of uninsurance or a shorter one, there would be nothing to prohibit a child from being enrolled in that portion of the program even if the family had recently dropped coverage under its group health plan. There is no reason

that States should not be allowed to offer such coverage, although we believe it is unlikely that many families will drop their private group health insurance for coverage under a State's separate child health program, in part because most families would prefer to keep coverage of all the family members under one plan.

Comment: Many commenters suggested inclusion in the regulation of a mandatory list of exceptions to the proposed minimum 6-month waiting period and also encouraged the Department to prohibit waiting periods in excess of six months. Suggested exceptions included when: (1) An eligible individual is pregnant or disabled; (2) a waiting period exceeds the 63-day gap limit under HIPAA and would result in exclusion of coverage for a preexisting condition under the coverage offered by the State's separate child health program; (3) an eligible child is a newborn or recently adopted; (4) the waiting period would block coverage of a well-baby, well-child, or immunization service according to the periodicity schedules for such services; (5) insurance is lost because of involuntary job loss; (6) insurance is lost because of death of a parent; (7) insurance is lost because of a job change to employment where the new employer does not cover dependents; (8) a family moves out of the service area of employer coverage; (9) an employer terminates insurance coverage for all of its employees; (10) COBRA insurance benefits expire; (11) employment-based insurance ends because an employee becomes self-employed; (12) insurance is lost because of long-term disability; (13) insurance is terminated due to extreme economic hardship of the employer or employee; and (14) there is a substantial reduction in lifetime medical benefits or benefit category to an employee and dependents in an employee-sponsored plan. One of the commenters also suggested an exception when there has been a loss or termination of employer-based coverage due to affordability problems that would be determined based on a percentage of income. In addition, some commenters suggested exceptions when an eligible child has insurance that only provides limited coverage such as catastrophic coverage, hospital-only coverage, or scholastic coverage with very high deductibles, because these policies wouldn't allow access to preventive medical benefits.

Response: HCFA encourages States that impose waiting periods without group health coverage to consider adopting exceptions. Many States have adopted exceptions to the period of uninsurance based on a variety of factors. We have approved exceptions for reasons such as: loss of insurance due to involuntary job loss, death of a parent, change of employment where the new employer does not cover dependents; a family moved out of the service area of employer coverage; employer termination of insurance coverage for all employees; expiration of COBRA insurance benefits; end of employment-based insurance because an employee becomes self-employed; loss of insurance because of a long-term disability; termination of insurance due to economic hardship of the employer; when the family faces extreme economic hardship; and a substantial reduction in lifetime medical benefits to an employee and dependents in an employer-sponsored plan.

We have made several changes to the list of exceptions to the minimum period without coverage under a group health plan. States may allow for exceptions to the minimum period without coverage under a group health plan when the child's coverage is involuntarily terminated due to employer termination of coverage for all employees and dependents. We have added an exception for cases when there is a change in employment that does not offer dependent coverage.

In addition, States may provide an exception when the child's family faces economic hardship. While States have flexibility to define this term, examples of economic hardship could be families who are facing unusual economic difficulties, such as the loss of a home to fire, or high out-of-pocket costs due to a family member's illness not being covered by insurance. Another example would be if a State is targeting its premium assistance program to certain employers that provide only very limited health insurance coverage, a waiting period may not necessarily be required since the likelihood of substitution would be limited in those circumstances. Finally, we would consider an exception to the waiting period requirement if a State's proposal targeted low-wage employers in its premium assistance program, because substitution is much less likely when the coverage being subsidized is offered only by low-wage employers.

We anticipate that these reasonable exceptions will help facilitate States' ability to utilize premium assistance programs to enroll children in SCHIP.

Comment: One commenter noted that their State has had a Health Insurance Premium Payment (HIPP) program for Medicaid since July 1991. Under the HIPP program, the State pays the entire cost of the employee's share of the premium necessary to provide coverage to the Medicaid-eligible family members. Based on the State's experience with this program, they stated that they do not agree with our position that allowing States to assist families in the purchase of employer-related coverage will result in substitution of coverage. In fact, the commenter noted that as a condition of Medicaid eligibility, this State requires the family to maintain the insurance when it is cost-effective for the State to buy the coverage. This State argued that its policy supports the provision of premium assistance for employer coverage and avoids substitution because the State maintains the coverage for the family.

The commenter believed that HCFA's position actually promotes substitution of coverage by making it harder for States to buy-in to employer health plans when they become available and, thus, depriving the State of the opportunity to buy coverage that is more cost effective to the State.

The commenter was particularly concerned about our proposal because they have a strong HIPP program. It appears to the commenter that, if the State is purchasing employer coverage under the HIPP program for a Medicaid-eligible child, at the time the child transitions to their separate SCHIP program, the child has health insurance through an employer (although the State was paying for it), would result in the imposition of a 6-month waiting period before the child could be eligible for SCHIP and before the State could continue buying-in to the employer coverage. The commenter wanted the flexibility to maintain employer-sponsored coverage for children when they transition between Medicaid and the separate SCHIP program.

Response: We understand the commenter's concerns and acknowledge that substitution policies raise complex issues for which there are no clear answers. We have revised our policy in a number of ways to allow States greater flexibility to design premium assistance programs and we will continue to work with States as they evaluate how these programs are working and whether employer contributions are maintained. We note that in Medicaid, unlike SCHIP, having other health insurance coverage does not preclude eligibility for the program. With respect to the problem suggested by the commenter, we note that waiting periods do not apply when a child moves from a Medicaid program into a separate child health program because of an increase in family income, even if the Medicaid coverage was provided through an

employer-based plan such as the case with the HIPP program. In this case the child would be considered to have been covered by Medicaid, rather than by group health insurance coverage.

Comment: One commenter noted that if a family has to be uninsured for six months before the children can receive coverage through premium assistance for a group health plan, the family may miss the employer's open enrollment period while it waits to have access to premium assisted coverage.

Response: We note that the minimum waiting period requirement applies to the SCHIP-eligible child, not the entire family. Thus, for example, a parent could elect self-only coverage and decline dependent coverage, and enroll immediately in the employer-sponsored health insurance. Then, once the six-month waiting period had been satisfied, the parent could enroll the child(ren) at the next open enrollment period and obtain SCHIP premium assistance. States may cover SCHIP-eligible children in their regular SCHIP programs until such time as they can be enrolled in employer plans. Because § 457.810 gives effect to an important congressional purpose related to SCHIP coverage, we are maintaining the minimum waiting period in this circumstance. However, we suggest that States adopt rules, under the scope of their regulatory authority consistent with HIPAA, to require a special enrollment opportunity in group health plans based on a SCHIP-eligible individual or family becoming eligible to enroll in the plan under a premium assistance program.

Comment: One commenter suggested that the general provisions of proposed § 457.805, which say that ''The State plan must include a description of reasonable procedures to ensure that coverage provided under the plan does not substitute for coverage under group health plans . . . '' are sufficient and that proposed section § 457.810 (''Premium assistance programs: Required protections against substitution.'') should be deleted in order to allow States the flexibility to develop innovative approaches to utilizing employer-sponsored insurance coverage for SCHIP enrollees. The commenter indicated its belief that this approach would be in accord with Congress' intent that SCHIP programs be State-designed and State-operated, and that it would allow for the fact that private insurance markets and employer-sponsored health insurance patterns vary significantly from State to State. Proposed § 457.810 would make it very difficult for the implementation of employer-sponsored insurance under SCHIP.

Response: We understand the commenters concerns and have added some significant flexibility in this section of the final rule, as discussed above. We will work closely with States to develop premium assistance programs that fit their needs in the simplest and most operationally efficient way possible, while complying with the provisions of this final rule.

Comment: One commenter suggested that the language in § 457.810(a)(1) is poorly drafted and appears to imply that children uninsured more than 12 months would not be provided SCHIP coverage.

Response: We agree and have revised the language in § 457.810(a)(1) to clarify that a State, may not require a waiting period that exceeds 12 months.

H. Subpart I—Program Integrity

We proposed in subpart I to specify the provisions necessary to ensure the implementation of program integrity measures and enrollee protections within the State Children's Health Insurance Program. In addition, this subpart discussed the President's Consumer Bill of Rights and Responsibilities as it relates to the SCHIP program. This subpart also described how the intent of the GPRA can be upheld by including program integrity performance and measures as part of the State plans.

The grievance and appeal, and privacy-related issues addressed under this Subpart of the proposed regulation are now being addressed in the new Subpart K, Applicant and Enrollee Protections.

1. Basis, Scope, and Applicability (§ 457.900)

In § 457.900, we proposed under the authority of sections 2101(a) and 2107(e) of the Act to set forth fundamental program integrity requirements and options for the States. Section 2101(a) of the Act specifies that the purpose of the State Children's Health Insurance Program is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. In addition, section 2107(e) of the Act lists specific sections of title XIX and title XI and provides that these sections apply to States under title XXI in the same manner they apply to a State under title XIX.

The program integrity provisions contained in this subpart only apply to separate child health programs. States that implement a Medicaid expansion program are subject to the Medicaid program integrity provisions set forth in the Medicaid regulations at part 455, Program Integrity: Medicaid.

Comment: One commenter suggested that HCFA meet with the Office of the Inspector General to discuss fraud and abuse issues related to outreach to look at the legality of encouraging certain outreach strategies. The commenter noted that payment from a particular provider to a person, who the provider knows or should know would be likely to influence the individual to receive services, is prohibited.

Response: We appreciate the concern of the commenter. We routinely coordinate with the OIG regarding the review of existing and proposed regulations in accordance with the Inspector General Act, section 4(a)(2).

Comment: One commenter recommended that the entire Subpart be revised to be consistent with the requirements in the Medicare program. The commenter urged HCFA to adopt detailed requirements for both fee-for-service and managed care claims and suggested extensive revisions to the proposed rules. The commenter felt the need for flexibility did not justify State-by-State variation with respect to the applicability or enforcement of the False Claims Act.

Response: We disagree with this comment. The Medicare program is nationally funded and administered, while Medicaid and SCHIP are jointly-funded Federal-State programs that are administered by the States within broad Federal guidelines. Therefore, it would be inappropriate and infeasible to require SCHIP and Medicaid programs to conform to fraud and abuse prevention standards of an entirely Federally funded and administered program. In addition, while we recognize the significance of the False Claims Act, standardized claims requirements are not necessary for the efficient and effective operation of the SCHIP program, or for enforcement of the False Claims Act.

Comment: One commenter felt that HCFA over-emphasized the issue of program integrity at this point in the implementation process. They suggest that the States' scarce resources and personnel would be better focused on outreach, eligibility and enrollment rather than program integrity and fraud. This commenter commended our emphasis on the need for continuity with other State programs. One commenter recommended deleting §§ 457.915, 457.920, 457.925, and 457.930 because the commenter felt that the proposed rule should not mandate State activities that are subject to the

administrative cap and that are not specifically required in the statute.

Response: While we appreciate the commenter's concern, we disagree with the commenter's argument that we over-emphasized program integrity too early in the implementation process. We agree that outreach, eligibility, and enrollment are all important aspects of SCHIP programs and deserve adequate resources for development and implementation. However, program integrity initiatives are also necessary now that States' programs have been established. Program integrity is essential to protecting the SCHIP program from abuse and to ensuring that the program serves those it was intended to serve, uninsured low-income children. Therefore, to protect public funds from inappropriate and unintended uses and to preserve the SCHIP program, States must have a strong fraud prevention and detection plan early in program development so that it will be in place as programs develop and mature, and serve as a viable deterrent to potential fraud and abuse.

Comment: One commenter requested clarification on the issue of limitations on provider taxes and donations as it applies to the provider contribution toward family cost-sharing requirements.

Response: The donation rules at section 1903(w) of the Act govern donations by providers or related entities directly to the State, or to extinguish a State liability. Premiums are a liability of the recipient. When donations are given to the recipient, or to the State on behalf of the recipient, the liability of the recipient is reduced, not the liability of the State. As a reasonable safeguard, the sponsor paying the premium on behalf of the enrollee should either give the donation directly to the family, make the donation to the State tied to specific eligible individuals, or make the donation to the State which will in turn, designate the specific eligible individual(s). In the latter case, the State must assure donations are assigned to enrollees in a manner that does not favor higher income children over lower income children. In any case, the donation should not exceed the premium amount specified in the approved title XXI State plan. The section of the State plan related to cost sharing should describe the procedure for accepting such donations.

In addition, we note that providers are prohibited from giving enrollees anything of value that is likely to induce an enrollee to select a particular provider under the provisions of section 1128A(a)(5). Such conduct may subject the provider to civil monetary penalties under that section. This civil money penalty provision is administered by the Office of the Inspector General (OIG). In general, States are advised to avoid donations from providers for enrollee premiums that could unduly influence enrollees to select a particular health plan or provider. A State that is concerned that donations for enrollee's premiums may violate these provisions may wish to seek an advisory opinion from the OIG. See 42 CFR part 1008. The OIG will also participate in review of State plans or amendments proposing such donations.

Comment: One commenter noted that the many requirements included in this Subpart tacitly assume that the State will have a direct, contractual relationship with all SCHIP participating health plans, including premium assistance plans. However, they stated that, for premium assistance programs for group health coverage, no such contractual mechanism will exist. The employer, not the State, is the entity that contracts with the health plan; and the State is simply providing premium assistance to enable families to enroll their children in premium assistance programs, according to this commenter. Because there is no mechanism for enforcement here, the commenter stated that they are assuming that the requirements in this Subpart would not apply to employer plans. They suggested that the preamble should clarify this point. They cautioned that any attempt to apply requirements of this sort to employer plans will mean that no employer plans will ever qualify for premium assistance.

Response: While we have considered the commenter's concerns, States are responsible for the oversight of the use of public funds to provide child health assistance through premium assistance programs just as they are responsible for oversight in other types of children's health insurance programs. Consequently, it is not appropriate to make an exception from program integrity regulations for employer plans. In the case where the State has no direct contractual relationship with the entity providing health coverage, the State should utilize the fraud protections provided through the State insurance agency responsible for oversight of all commercial plans. For example, if State funds are provided under SCHIP to State-regulated health plans, the State insurance department anti-fraud component could conduct the State's anti-fraud oversight for its SCHIP funds. This final regulation provides flexibility to States for States to develop program integrity methods and systems that fit the needs of their particular SCHIP programs, whether or not those programs consist of premium assistance for group health plans.

2. Definitions (§ 457.902)

We proposed five definitions for the purpose of this subpart. We proposed that ''contractor'' means any individual or entity that enters into a contract, or a subcontract, to provide, arrange, or pay for services under title XXI. This definition includes, but is not limited to, managed care organizations, prepaid health plans, primary care case managers, and fee-for-service providers and insurers.

We proposed that a ''managed care entity'' is any entity that enters into a contract to provide services in a managed care delivery system, including, but not limited to managed care organizations, prepaid health plans, and primary care case managers. We proposed that ''fee-for-service entity'' means any entity that provides services on a fee-for-service basis, including health insurance services. We proposed that ''State program integrity unit'' means a part of an organization designated by the State (at its option) to conduct program integrity activities for separate child health programs.

Finally, we proposed to define the term ''grievance'' as a written communication, submitted by or on behalf of an enrollee in a child health program, expressing dissatisfaction with any aspect of a State, a managed care or fee-for-service entity, or a provider's operations, activities, or behavior that pertains to specified areas, including the availability, delivery or quality of health care services, payment for health care services and other specified areas. The grievance and appeal, and privacy-related issues addressed under this Subpart of the proposed regulation are now being addressed in the new Subpart K, Enrollee Protections.

Comment: A few commenters suggested that the definitions of ''fee-for-service entity'' and ''contractor'' raised a potential inconsistency in that the term ''fee-for-service entity'' does not include ''individual or entity'' as ''contractor'' does. This suggests that individual physicians or other practitioners are exempted from the requirement at § 457.950 to attest that any claims submitted for payment to be accurate, complete and truthful. The commenters noted that these practitioners are currently required to make this certification under Medicare and Medicaid.

Response: We agree with the comment and have modified the regulation text accordingly. We note again that we have created a new subpart intended to address more specifically the issues related to enrollee protections and because the term ''contractor'' will now apply to both this subpart and the new subpart K, we have moved the definition to § 457.10.

3. State Program Administration (§ 457.910)

In § 457.910 we proposed that the State child health plan must provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the separate child health program. We also proposed that the State's program must provide the safeguards necessary to ensure that eligibility will be determined appropriately in accordance with Subpart C of this regulation, and that services will be provided in a manner consistent with administrative simplification and with the provisions of Subpart D—Coverage and Benefits.

Comment: One commenter noted that the preamble language states that the Secretary wishes to give States ''maximum flexibility'' in the administration of their SCHIP programs. However, the commenter felt that the literal interpretation of this language translated into ''methods of administration that the Secretary finds necessary,'' giving the Secretary too much discretion to impose methods of administration on States.

Response: We understand the commenter's concerns. The commenter is correct that the Secretary has a great deal of discretion over the requirements of the SCHIP program. We remain committed to providing States with flexibility in the administration of their SCHIP programs but, as stated in the preamble to the proposed regulation, we seek to balance this need against the Federal government's need to remain accountable for the integrity of the program. The provisions of the regulation reflect this balance and the basic framework within the regulation is necessary to ensure the integrity of SCHIP. However, this framework does not dictate to the States what methods of administration they must use to prevent and detect fraud and abuse, thereby leaving the States with significant flexibility to administer SCHIP programs.

Comment: One commenter encouraged HCFA to ensure administrative simplification, not only in the operation of the program, but in the provision of services and with respect to providers.

Response: HCFA is committed to policy approaches that minimize the administrative burden that is placed on States in implementing their SCHIP programs in general. In addition, we are mindful of the need to strike a balance between ensuring access to SCHIP coverage, and the benefits provided under that coverage, without making it unduly burdensome for States to accomplish these goals. However, these rules address State requirements and are not intended to address State relationships with providers, which are a contractual matter between the State and providers.

4. Fraud Detection and Investigation (§ 457.915)

Section 2107(e) references sections 1903(i)(2) and 1128A of the Act, which provides a basis for certain fraud detection and investigation activities. Section 2107(e) states that these provisions apply under title XXI in the same manner as they apply to a State under title XIX. Moreover, these provisions are cited as authority in the Medicaid regulations at part 455, Subpart A—-Medicaid Agency Fraud Detection and Integrity Program. In the proposed rule, we discussed in detail three possible options we considered to ensure that separate child health programs develop and implement adequate fraud detection and investigation processes and procedures. We concluded that the best approach would be to require States to address, specifically, the Medicaid goals for fraud detection and investigation, but to allow States to design specific procedures needed to meet the requirements of § 455.13. We chose neither to require States with separate child health programs to follow the same procedures for fraud detection and investigation as the Medicaid program, nor did we provide States with full latitude in designing processes and procedures. We stated that this approach balances the need for maintaining State flexibility while establishing an acceptable minimum standard that will satisfy our need for accountability in the program.

We proposed that the State must establish procedures for assuring program integrity and detecting fraudulent or abusive activity. We also proposed that the procedures must include, at a minimum, the methods and criteria for identifying suspected fraud and abuse cases as well as methods for investigating fraud and abuse cases that do not infringe on the legal rights of persons involved and afford due process of law. The State may establish an administrative agency responsible for monitoring and maintaining the integrity of the separate child health program, which is referred to in subsequent provisions of the regulation as the ''State program integrity unit''. We further proposed that the State must develop and implement procedures for referring suspected fraud and abuse cases to the State program integrity unit (if such a unit is established) and to law enforcement officials. Law enforcement officials include, but are not limited to, the Department of Health and Human Services Office of Inspector General (OIG), the Department of Justice (DOJ), the Federal Bureau of Investigation (FBI), and the State Attorney General's office.

Comment: One commenter commended HCFA for recognizing that separate child health programs should not be expected to have the same fraud detection and infrastructure as required under Medicaid. However, the commenter felt that by tying goals to Medicaid fraud and abuse goals, as well as recommending the use of the State program integrity unit, HCFA was pushing the States toward Medicaid procedures without backing them up with sufficient funding levels.

Response: While we understand the commenter's concern, we specifically set out in the proposed rule a framework that attempted to provide flexibility to the States, while ensuring that States include basic, necessary protections against fraud. We are not requiring States to establish State program integrity units or to use Medicaid fraud and abuse methods or procedures to ensure the integrity of the SCHIP program. We invite States to design program integrity plans and procedures that are specific to the needs of their unique SCHIP programs within the broad framework required by the final rule. The flexibility afforded the States in this regulation allows them to structure program integrity activities that limit the administrative burden, but still ensure the integrity of the program.

Comment: One commenter found the rules overly prescriptive and recommended the elimination of paragraph (b) that describes the ''State program integrity unit'' and the deletion of the requirement to refer program integrity cases to law enforcement officials in (c).

Response: The rule encourages, but does not require, States to develop or use an entity that could be called a ''State program integrity unit''. This concept was developed in an attempt to give the States a framework to set up an effective program integrity strategy. While not required, we believe the

development of such a unit would be very beneficial to the States in designing systems to address these issues. In addition, because of Medicaid statutory provisions, States are not permitted to use existing Medicaid fraud control units (MFCUs) to conduct SCHIP program integrity activities. (While MFCUs have been given additional flexibility under the Ticket to Work Incentives Improvement Act of 1999, this flexibility only applies in cases that primarily involve Medicaid funds.) In general, States are limited to using Medicaid funds for Medicaid activities. If a State wanted to utilize the MFCU, it could only do so by hiring new staff that would be exclusively responsible for SCHIP program integrity activities and are funded by title XXI funds. (We note that this new, separately funded ''branch'' of the MFCU could be called the ''State program integrity unit''.) Therefore, we will not eliminate § 457.915(b). Finally, the inclusion of, and coordination with, appropriate Federal and State law enforcement officials as part of a State's overall fraud detection efforts, and overall program integrity efforts, is vital to the effectiveness of its program integrity activities. Therefore, we will not eliminate § 457.915(c).

Comment: Several commenters noted that they appreciated the need for fraud and abuse protections, and hoped HCFA was allowing flexibility for States to utilize provider fraud detection processes of participating health plans or other State insurance department procedures. Also, these commenters hoped that States would be given sufficient time to implement these procedures.

Response: These final rules provide a structure under which States have the flexibility to use a variety of methods to create a comprehensive fraud detection strategy. While we envision that the State insurance departments may play an important role for a State in SCHIP fraud and abuse detection and investigation, we anticipate that States may want to complement those procedures already performed by the State insurance departments with procedures and goals specific to SCHIP. Specifically, fraud and abuse stemming from procedures for, or other aspects of, participant enrollment in the separate child health program would raise distinct issues that likely fall outside of procedures established by State departments of insurance as they monitor private health plans and issuers outside of the SCHIP context. States must also address the concern that fraud and abuse may occur within a participating health plan apart from provider fraud and therefore, States must have additional procedures to detect and investigate fraud within plans. Therefore, relying on plans' processes to monitor provider fraud, while potentially useful, would not sufficiently protect against the varied types of fraud and abuse that could impact the SCHIP program in a State.

We note the commenters' concern that States need a reasonable amount of time to implement new Federal requirements. We will require that States come into conformity with new requirements within 90 days of publication of this rule, or if contract changes are necessary, the beginning of the next contract cycle. In limited cases where a new regulatory provision requires a description of procedures in the State plan, then the State must implement the procedures within the above time frame and submit the State plan amendment in compliance with § 457.65(a)(2).

Comment: One commenter noted that precise, professional guidelines regarding care issues, industry-accepted standards for fair and reasonable audits, and investigations with due process protections for providers, are essential to expand access under SCHIP.

Response: The best means of expanding access to care under SCHIP is to allow the States sufficient flexibility in designing program integrity procedures and methods as well as other aspects of their programs while maintaining a framework of Federal requirements consistent with title XXI. We encourage States to develop precise, professional guidelines as part of the design of State fraud detection and investigation methods. In addition, States should refer to industry standards in establishing audit processes as appropriate. Section 467.915(a) specifies that States must establish procedures for investigating fraud and abuse cases that do not infringe on legal rights of persons involved and afford due process of law. These requirements apply to investigations of all types of fraud and abuse under the separate child health program, including investigations that involve providers.

Comment: One commenter recommended that the language in this section be expanded to include use of procedures already in place that support these activities. In addition, they suggested revising § 457.915(c) to clarify that suspected fraud and abuse cases should be referred to ''appropriate'' law enforcement officials as determined by State law.

Response: We have revised the regulation text at § 457.915 to clarify that States must develop and implement procedures for referring suspected fraud and abuse cases to appropriate law enforcement officials, although we have not included the commenters' recommended language ''as determined by State law'' because referrals could be made to Federal law enforcement officials, as appropriate. We have listed certain law enforcement officials under § 457.915(c) because States may wish to contact these officials with fraud and abuse information to facilitate program coordination. This is not intended to be an exhaustive list of all law enforcement officials States may contact, nor is referral to all these entities required, unless it is appropriate.

5. Accessible Means To Report Fraud and Abuse (§ 457.920)

We proposed that States with separate child health programs must establish, and provide access to, a mechanism of communication between the State and the public about potentially fraudulent and abusive practices by and among participating contractors, beneficiaries, and other entities. We noted in the preamble to the proposed regulation that this communication mechanism may include a toll-free telephone number, and also noted that States are free to use their discretion regarding whether to establish toll-free services for these purposes alone or to expand upon existing services. We noted that access to toll-free service for the reporting of potentially fraudulent and abusive practices is a integral part of any sound program integrity strategy.

Comment: One commenter recommended that this provision be deleted because the rule should not mandate State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: We acknowledge the commenters' point and agree that this section should be deleted. However, we have deleted this section because while we do have statutory authority to include such a provision, the provision was unnecessary and somewhat redundant.

6. Preliminary Investigation (§ 457.925)

We proposed that if the State receives a complaint of fraud or abuse from any source, or identifies any questionable practices, the State agency must conduct a preliminary investigation or take otherwise appropriate action to determine whether there is sufficient basis to warrant a full investigation. We noted in the preamble, consistent with § 457.915(b), that the State has the option of creating a ''State program integrity unit'' for separate child health

programs that would be responsible for monitoring and maintaining the integrity of the separate child health program. We also noted that each State has flexibility to define the role played by such units but that fraud and abuse activities relating to SCHIP must be funded with monies from the State's SCHIP allotment. Finally, while we proposed that preliminary investigations be conducted under the circumstances specified in § 457.925, we remained flexible with regard to the processes and procedures that separate child health programs employ in conducting preliminary investigations and did not require or specify the procedures States must take to conduct their investigation in compliance with this requirement.

Comment: One commenter recommended that this provision be deleted because the rule should not mandate State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: We disagree that this section should be deleted. As noted earlier, we maintain that these program integrity activities are necessary for the effective and efficient administration of the State plan as required in § 2101(c)(2) of the statute, in addition to being based on the sound precedents set by the Medicare and Medicaid programs.

Comment: One commenter recommended that HCFA specify that States must undertake a preliminary investigation within a reasonable time not to exceed 60 days.

Response: We agree with the commenter's suggestion that a State must undertake a preliminary investigation within a certain amount of time. We have not prescribed a specific number of days, but suggest that 60 days is indeed a reasonable amount of time to undertake a preliminary investigation. We have made the appropriate change to the regulation text.

7. Full Investigation, Resolution, and Reporting Requirements (§ 457.930)

We proposed that the State must establish and implement effective procedures for investigating and resolving suspected and apparent instances of fraud and abuse. We further proposed that, once the State determines that a full investigation is warranted, the State must implement certain procedures, including, but not limited to, the procedures specified at paragraphs (a) through (c) of § 457.930.

We noted in the preamble to the proposed rule that States may model their approaches after procedures for fraud and abuse investigation, resolution, and reporting used by the Medicaid State agency as outlined in §§ 455.15, 455.16, and 455.17 of the Medicaid regulations. Medicaid funding cannot be used for fraud investigation activities in separate child health programs. MFCUs may only use Medicaid funding for fraud and abuse activities in States that provide child health assistance under a Medicaid expansion program. MFCU professional staff being paid with Medicaid dollars must be full-time employees of the Medicaid fraud agency and devote their efforts exclusively to Medicaid fraud activities. To the extent that States want to allocate additional non-MFCU full-time staff, using SCHIP dollars, to work exclusively on fraud and abuse investigation in separate child health programs, they may do so. We noted that expenditures for this purpose would be subject to the 10 percent cap on administrative costs under section 2105(c)(2) of the Act.

Comment: One commenter suggested that a better alternative to traditional law enforcement would be to work through the provider fraud processes established by participating health plans, under which the expenditures might be considered a benefit cost rather than an administrative cost.

Response: While we intended to provide flexibility in implementing program integrity strategies, as noted in response to a comment on § 457.915, States must be aware that fraud and abuse may stem from within a participating health plan or apart from providers. Therefore, States must have procedures at the State level to detect and investigate plan and issuer fraud and abuse, as well as provider fraud and abuse. Relying on plan and issuers to monitor themselves for fraud and abuse would not be in the public interest.

It is true that capitated payments made to plans in conjunction with the provision of health benefits coverage that meets the requirements of title XXI and for which the plan is at risk are not considered administrative costs. Therefore, plan activities covered by these payments are considered as expenditures for child health assistance. However, health plan processes for the detection, investigation and resolution of fraud and abuse, and that protecting program integrity is not the only concern States must consider in designing their program integrity strategies. They must design strategies that accomplish the goals of, and comply with the requirements of, this subpart, thereby protecting against a range of potential fraud and abuse concerns, such as, but not limited to, any potentially problematic health plan activity.

Comment: Several commenters recommended that HCFA allow States the authority to enter into agreements with other investigative bodies, not strictly law enforcement officials, and not necessarily a State-established program integrity unit; rather, they recommended that States be able to contract with bodies such as health plan investigative divisions. To this aim, commenters recommended paragraph (c) be rewritten to include referring the fraud and abuse case to an appropriate investigative body as designated by the State.

Response: We agree that States should be able to structure their fraud and abuse activities in different ways; however, the inclusion of coordination with any law enforcement officials is an integral part of an effective program integrity process. We have modified the regulation text to clarify that State should be able to determine the appropriate law enforcement officials to whom they should refer suspected fraud and abuse cases but we do not agree with the recommendation that States should not have to coordinate with any law enforcement officials. We reserve the right to review the States' program integrity procedures to ensure their compliance with the requirements and goals of title XXI and this regulation.

Comment: One commenter believed that it is unreasonable to judge States' applications or amendments based on consistency of their fraud and abuse procedures with other State programs.

Response: States are required to design and implement procedures for fraud investigation, resolution, and reporting. States are not required to file State plan amendments with HCFA in order to implement a program integrity fraud and abuse detection and investigation strategy. Therefore, HCFA will consider State's statement assuring the development and implementation of a program integrity system to be a requirement that is subject to review through HCFA's ongoing monitoring.

Comment: We received a few comments noting that requiring States with separate child health programs to set up separate structures other than Medicaid Fraud Control Units to do the same function is a waste of resources, and that requiring separate processes is burdensome and costly. One commenter recommended that States have the option to allow the MFCU to conduct SCHIP fraud investigations, assuming tracking and claiming are conducted appropriately. Another commenter recommended deleting the provision because the rule should not mandate

State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: As noted above, the Medicaid statute does not permit MFCUs to conduct program integrity activities that are not related to the Medicaid program. We disagree that this section should be deleted. We maintain that program integrity activities are necessary for the effective and efficient administration of the State plan as required in section 2101(c)(2) of the statute, in addition to being based on the sound precedents set by the Medicare and Medicaid programs. While we recognize that some of these activities could be duplicative, we do not have the authority to blend the funding for fraud and abuse prevention efforts among the Medicaid and SCHIP programs.

Comment: One commenter suggested that States must have *written* procedures for investigating and resolving suspected and apparent instances of fraud and abuse.

Response: We agree that States should have written procedures for investigating and resolving suspected and apparent instances of fraud and abuse to ensure the effective and efficient administration of SCHIP programs. However, we are not requiring that States submit to HCFA such written procedures. We anticipate that States may continue to develop and to modify fraud investigation and detection procedures as SCHIP programs develop. Therefore, we anticipate the methods and rules relating to program integrity will evolve as they are implemented. We wish to give the States the flexibility to improve fraud and abuse detection systems as they develop, rather than tying States to an initial written plan. However, HCFA reserves the right to review a States' program integrity procedures, and to request that they be described in writing, as part of its ongoing monitoring.

8. Sanctions and Related Penalties (§ 457.935)

Under the authority of sections 2101(a) and 2107(e) of the Act, and consistent with the requirements under Federal and State health care programs, we proposed that a State may not make payments for any item or service furnished, ordered, or prescribed under a separate child health program to any contractor who has been excluded from participating in the Medicare and Medicaid programs. We noted that this provision is necessary to implement section 1128 of the Act regarding exclusion of certain individuals and entities from participation in Medicare and State-administered health care programs. We proposed that the separate child health programs be subject to program integrity provisions set forth in the Act including: (1) Section 1124 relating to disclosure of ownership and related information; (2) section 1126 relating to disclosure of information about certain convicted individuals; (3) section 1128A relating to civil monetary penalties; and (4) section 1128B(d) relating to criminal penalties for acts involving Federal health programs. We also proposed to make separate child health programs subject to Part 455, subpart B of chapter IV of title 42 of the Code of Federal Regulations. In an effort to promote enforcement of this subsection and to provide HCFA and the Secretary with critical fraud and abuse data, we also proposed that the separate child health programs be subject to the requirements of section 1128E of the Act in the same manner as under the Medicare and Medicaid programs. In accordance with section 1128E of the Act, we proposed that the separate child health program be subject to the requirements pertaining to the reporting of final adverse actions on liability findings made against health care providers, suppliers, and practitioners. In addition, we noted in preamble that States should share such information and data with the Office of the Inspector General in an effort to promote enforcement.

We did not receive any comments on this section and will therefore implement the regulation language as proposed.

9. Procurement Standards (§ 457.940)

Section 2101(a) of the Act requires that States provide services in an effective and efficient manner. In order to meet our obligation to ensure that States use SCHIP funds in a cost-effective manner, we set forth provisions at proposed § 457.940 regarding procurement standards. The proposed provisions did not include Federal oversight of provider payments. Rather, we proposed to require that States set rates in a manner that most efficiently utilize limited SCHIP funds.

We proposed to require that States provide HCFA with a written assurance that title XXI services will be provided in an effective and efficient manner. We also proposed that the assurance must be submitted with the initial SCHIP plan or, for States with approved SCHIP plans, with the first request to amend the SCHIP plan submitted to HCFA following the effective date of these regulations.

If States contract with entities for SCHIP services, they must provide for free and open competition, to the maximum extent possible, in the bidding of all contracts for coverage or other title XXI services in accordance with the procurement requirements of 45 CFR 74.43.

Alternatively, we proposed that States may base title XXI payment rates on public or private payment rates for comparable services. We noted in preamble that this applies to fee-for-service and capitated rates. We proposed that, if a State finds it necessary to establish higher rates than would be established using either of the above methods, it may do so if those rates are necessary to ensure sufficient provider participation or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services. For example, this method will allow States the flexibility to establish higher rates to attract providers in under-served areas or to enroll more costly specialty providers.

We also proposed that States must provide to HCFA, if requested, a description of the manner in which they develop SCHIP payment rates in accordance with the requirements of §§ 457.940(b)(2) and (c). The description would include an assurance that the rates were competitively bid or an explanation of the applicability of the exceptions of 45 CFR part 74, or a description of the public or private rates that were used to set the SCHIP rates, if applicable, and/or an explanation of why rates higher than those that would be established using either of these two methods are necessary. HCFA may request the description when a State first determines its rates or, for approved SCHIP plans, when it updates its rates or changes its reimbursement methodology.

Comment: We received several comments recommending with regard to § 457.940(b)(1) that procurement standards in 45 CFR part 92 are more appropriate for non-entitlement programs such as SCHIP because they allow States to utilize their own procurement standards when purchasing services with Federal grant money. Flexibility will enable States to make cost-effective and quality health plan selections. One commenter noted that flexibility to establish higher rates to ensure provider participation should be coupled with stricter enforcement.

Response: We disagree with the commenter's suggestion for changing the procurement standards applicable to SCHIP. We believe the procurement requirements of 45 CFR 74.43 are more appropriate for separate child health

programs because they allow for accountability as well as State flexibility in implementation. We expect all States, not just those establishing higher rates to ensure provider participation or for other permitted purposes, to strictly enforce the procurement standards of this section.

Comment: Several commenters requested that § 457.940(b)(2) be rewritten as follows: ''Basing title XXI payment rates on public and/or private payment rates for comparable services for comparable populations.'' Several commenters felt this section should be expanded to allow States, where such comparisons cannot be made for lack of data, the ability to explain their analysis of why the rates are within acceptable parameters.

Response: We acknowledge the distinctions in rates that may need to be made based on the populations being served and have added ''for comparable populations'' to the regulation text as recommended. However, we disagree with the suggestion to change the regulation to allow States to explain why the payment rates are within acceptable parameters absent sufficient supporting data. The final regulation text includes a significant amount of flexibility for States to explain how they meet the standards of § 457.940(c) regarding the need for higher rates than otherwise permitted and received many comments recognizing its flexibility. We have retained the proposed language in § 457.940(c) regarding acceptable bases for such higher rates because we believe rates should only be permitted to be higher under those specific circumstances.

Comment: One commenter supported the intent of the section and noted the importance of setting adequate reimbursement levels to ensure provider participation and efficient provision of services. The commenter found it problematic that about half of the States set payment rates for separate child health programs at the same levels as they do for Medicaid. The commenter encouraged HCFA to work with States to establish more reasonable rates.

Response: Each State has the authority to set reasonable rates for its SCHIP population providers. It would be inappropriate for us to dictate to the States what specific rates they should pay to participating providers, especially in those States that have a sufficient number of providers to furnish quality care to all SCHIP participants. However, in accordance with § 457.495, we encourage States to set rates and generally administer their SCHIP programs in a way that will provide access to providers and attract an adequate number of highly qualified, experienced providers with the appropriate range of specialties and expertise.

Comment: One commenter suggested that HCFA incorporate a standard that the SCHIP rates for MCEs be actuarially sound and that we should clarify the meaning of actuarial soundness in the managed care context. In addition, another commenter suggested that HCFA require States to justify or prove the methodology used to establish the payment rate.

Response: We agree with the comment that rates should be actuarially sound. Actuarially sound capitation rates means that they have been developed in accordance with generally accepted actuarial principles and practices, that are appropriate for the populations and services to be covered under the contract, and that have been certified by an actuary (or actuaries) meeting the qualification standards established by the Actuarial Standards Board. The text of the regulation at § 457.940(b)(3) has been changed to reflect this and a definition is included at § 457.902—Definitions.

Comment: One commenter supported giving States maximum flexibility to take advantage of local market forces in establishing SCHIP payment rates. In this commenter's view, States should provide reimbursement for obstetric and gynecologic services sufficient to assure that SCHIP enrollees have access equal to that of privately insured patients. This commenter also noted that providing these types of services to adolescents is often quite time consuming due to the various developmental and psycho social issues they face, and recommended that compensation for physicians should be determined accordingly.

Response: We appreciate support for the policy of giving States flexibility in their procurement and rate setting. However, it is important for States to set rates high enough to provide sufficient access to, and quality of, care for all SCHIP participants for all services. However, it is not appropriate to specify the need for enhanced payment rates for certain types of providers or services in regulation. The requirement that States provide for free and open competition in procurement or demonstrate that their rates meet the requirements of (b) or (c) should ensure that SCHIP enrollees have access to providers that are compensated appropriately within their local health care markets.

Comment: We received one comment recommending that § 457.940(a) include a specific reference that States must comply with all applicable civil rights requirements in accordance with § 457.130.

Response: Section 457.130, contained in subpart A (which is the subpart that sets forth many general State plan requirements), requires States to include in their State plan an assurance that the State will administer their SCHIP program in compliance with applicable civil rights requirements. We maintain that this provision sufficiently assures this compliance.

10. Certification for Contracts and Proposals (§ 457.945)

In addition to the proposed requirements in § 457.950, which specify that contractors must certify that payment data is accurate, truthful, and complete, we proposed to specify in § 457.945 that entities that contract with the State under a separate child health program must also certify the accuracy, completeness, and truthfulness of information in contracts, and proposals, including information on subcontractors, and other related documents, as specified by the State.

Comment: One commenter asserted that the requirements in this section are overly burdensome for States. Because so many of the SCHIP programs utilize managed care delivery systems, the commenter noted that managed care entities are required, by virtue of executing their contracts with the States, to provide accurate, complete and truthful information. The commenter felt that a separate and distinct certification document is unnecessary.

Response: While we appreciate the administrative challenges States may face in implementing SCHIP programs, we do not believe the requirements of this section are overly burdensome for States. The unique nature of the SCHIP program and its relationship with plans and issuers merits the inclusion in contracts of the specific certifications required by this section, and that compliance with this standard will protect against fraud and abuse in this government-funded program. The commenter may have interpreted this provision to require a separate certification document but, in fact, the required certification could be provided as part of, or together with, any of the contracts or related documents into which the State and its contractors have entered, and should entail minimal additional administrative effort.

11. Contract and Payment Requirements Including Certification of Data that Determines Payment (§ 457.950)

At § 457.950, we proposed that when SCHIP payments to managed care

entities are based on data submitted by the MCE, the State must ensure that its contracts with MCEs require the MCE to provide enrollment information and other information required by the State. We also proposed that the State ensure that its contract requires the MCE to attest to the accuracy, completeness, and truthfulness of claims and payment data, upon penalty of perjury. As a condition of participation in the separate child health program, MCEs must provide the State with access to enrollee health claims data and payment data, as determined by the State and in conformance with the appropriate privacy protections in the State. We also proposed that managed care contracts must include a guarantee that the MCE will not avoid costs for services, such as immunizations, covered in its contract by referring individuals to publicly supported health care resources (for example, clinics that are funded by grants provided under section 317 of the Public Health Service Act).

We proposed that when SCHIP payments are made to fee-for-service entities, the State must establish procedures to ensure and attest that information on provider claim forms is truthful, accurate, and complete. We also proposed that, as condition of participation in the State plan, fee-for-service entities must provide the State with access to enrollee health claims data and payment data, as determined necessary by the State.

Comment: One commenter agreed that agents of the State need access to payment information and that payment decisions must not be made without proper information and involvement of providers.

Response: We appreciate support for the requirements in § 457.950 regarding State access to claims and payment data. As noted in the preamble, compliance with § 457.950(b)(2) requires States to establish procedures to ensure and attest to the accuracy of information on provider claim forms. The State thereby must involve the provider community to the extent necessary to comply with this requirement and the rest of § 457.950, as noted in the comments.

Comment: One commenter recommended amending this section to include a requirement to comply with applicable civil rights requirements in accordance with § 457.130.

Response: Section 457.130 requires States to administer the entire SCHIP program in compliance with the Civil Rights requirements noted in the title XXI statute and we maintain that this provision sufficiently assures compliance.

Comment: One commenter noted that the wording of this section is confusing. The commenter noted that because some States may make prospective monthly payments to MCEs on the first day of each month, the MCE may not have any information other than the enrollment forms from the State itself. These States may be unclear as to whether or not this section applies to their programs.

We also received a few requests that the requirement to attest to the accuracy and completeness of the data reflect that, to the extent that data is based on projections (e.g. premium rate submissions) that plans be permitted to attest to the accuracy to the best of their knowledge, information and belief. Another commenter requested deletion of the phrase ''under penalty of perjury'' from paragraph (a) because the requirements are already enforced through contractual language and penalties. Also, commenters requested clarification that complete data refers to data that includes all elements required by the State.

Response: One of the fundamental tenets of program integrity is the need for certification of payment-related information. Prospective monthly payments are based on certified payment-related information despite the fact that they are developed retrospective of the services delivered. The submission of enrollment forms does not constitute payment-related information.

While we recognize that the clause ''under penalty of perjury'' at § 457.950(a) may not have been appropriate for the entire paragraph, the Office of the Inspector General representatives indicated that it was an essential protection. Therefore, we have deleted ''under penalty of perjury'' from the general language of § 457.950(a), but left it in § 457.950(a)(2).

12. Conditions Necessary to Contract as a Managed Care Entity (MCE) (§ 457.955)

In addition to implementing program integrity protections at the State level, we proposed under § 457.955 that the State must ensure that MCEs have in place fraud and abuse detection and prevention processes. These processes would include mechanisms for the reporting of information to appropriate State and Federal agencies on any unlawful practices by subcontractors of or enrollees in MCEs. In order to maintain privacy protections for enrollees, we proposed that the reporting of information on enrollees would be limited only to information on violations of law pertaining to actual enrollment in the plan or to, provision of, or payment for, health services. Furthermore, we proposed that the State maintains the authority and the ability to inspect, evaluate and audit MCEs, as determined necessary by the State in instances where the State determines that there is a reasonable possibility of fraudulent or abusive activity.

We noted in the preamble that States that have Medicaid expansion programs and contract with MCEs under section 1903(m) of the Act may arrange for an annual independent, external review of the quality of services (EQR) delivered by each MCE as provided for under section 1932(c)(2) of the Act. States are permitted to draw down 75 percent FFP for this activity. States with separate child health programs are encouraged to provide for EQR of each MCE under contract to provide services to SCHIP enrollees; however, expenditures for EQR would be subject to the 10 percent limit for administrative expenses under section 2105(c)(2) of the Act.

Comment: Several commenters suggested that separate SCHIP programs should not be required or encouraged (as in the preamble) to use the Medicaid external quality review of services and that there is inequity in that Medicaid expansion programs receive 75 percent FMAP for this activity while stand-alone programs are required to stay within the 10 percent limit on administrative expenditures.

Response: While the Medicaid EQR process is a good model for States implementing separate child health programs, we are not requiring the use of this process in the regulation text, therefore States have flexibility in determining the type of quality assurance processes they utilize. Thus, States retain discretion in the use of funds for administrative expenditures and how to stay within statutory limits on such expenditures.

Comment: One commenter recommended that HCFA clarify what action by MCEs are necessary to meet the requirement that MCEs contracting under a separate child health plans have administrative and management arrangements or procedures to safeguard against fraud and abuse. The commenter asked how this requirement differ from the M+C program requirement that each M+C organization have a compliance plan. This commenter also recommended that our guidance convey that the reporting requirement in this section should only apply after the completion of a reasonable inquiry and a finding of credible evidence that a violation has occurred.

Response: We did not attempt to make the provisions of this subpart consistent

with the M+C rule. As noted previously, the Medicare program is nationally-funded and administered; while Medicaid and SCHIP are funded by a combination of State and Federal funds.

We have, however, added a provision at § 457.955(b)(2) to specify that States must ensure arrangements that prohibit MCE's from conducting any unsolicited contact with a potential enrollee for the purpose of influencing an individual to enroll in the plan. This provision is added in order to prevent past abuses in which potential enrollees were influenced to join an MCE without the benefit of adequate information and education about their options in choosing an MCE and is consistent with similar provisions in Medicaid managed care, and Medicare+Choice.

Comment: We received one comment recommending that as a condition of qualification as an MCE contractor, the MCE must allow the States to inspect and audit MCEs at any time, when there is a reasonable possibility of fraud and abuse. This condition should also apply to any provider under contract to provide SCHIP services, according to this commenter.

Response: Section 457.955(d) of the NPRM states that ''the State may inspect, evaluate, and audit MCE's at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent and abusive activity.'' The regulation places the burden on the State to make sure that its contracts or arrangements with MCEs allow the State to comply with this section.

13. Reporting Changes in Eligibility and Redetermining Eligibility (§ 457.960)

We proposed in this section that States choosing to require that enrollees, or their representative, report changes in their circumstances during an eligibility period, the State must: (1) establish procedures to ensure that beneficiaries make timely and accurate reports of any changes in circumstances that may affect eligibility; and (2) promptly redetermine eligibility when it receives information about changes in a child's circumstances that may affect his or her eligibility.

Comment: One commenter noted that at redetermination, a child enrolled in a separate child health plan who becomes eligible for Medicaid should have a reasonable opportunity to apply and be found eligible for Medicaid without a break in coverage. The rules should specify that the child might remain enrolled in the separate child health program for up to 45 days (or longer if cause exists) while the Medicaid application is being processed in accordance with § 457.360. In addition, the rules should specify that prior to any termination of SCHIP coverage, the State should screen for potential Medicaid eligibility and facilitate enrollment.

Response: We agree with the goal of providing seamless coverage to all children eligible for Medicaid or SCHIP. See subpart C for requirements regarding screening and enrollment. These requirements apply to both eligibility determinations and redeterminations as specified at § 457.350(a).

Comment: One commenter recommended that HCFA provide guidance regarding how the redetermination process should be conducted. States should not be permitted to request a re-application or require that enrollees provide information that is not needed to complete the eligibility determination. States should also be required to give the enrollee adequate time to respond to requests for additional information. States must also be required to describe in the State plan how the child will be enrolled in Medicaid without a break in coverage.

Response: We recognize the concerns of the commenter, however, the NPRM balances the need for maintaining State flexibility while establishing an acceptable standard that will satisfy our need for accountability in the program. It would be inappropriate for us to dictate methods of redetermination or a specific redetermination process that all States must use. Rather, we are concerned that States have a redetermination process because SCHIP programs are best served by leaving the specifics of the process to each State.

14. Documentation (§ 457.965)

To ensure the integrity of the program, we proposed to require that the State include in each applicant's record certain facts that would, if necessary, support the State's determination of a child's eligibility. This documentation should be consistent with standard State laws and procedures.

We did not receive any comments on this section. Therefore, we are implementing this provision as set forth in the proposed rule.

15. Eligibility and Income Verification (Proposed § 457.970)

In this final regulation, proposed § 457.970 has been moved from subpart I to subpart C, Eligibility to become § 457.380. We have addressed comments on proposed § 457.970 in subpart C.

16. Redetermination Intervals in Cases of Suspected Enrollment Fraud (§ 457.975)

We proposed in § 457.975 that if a State suspects enrollment fraud, the State may, at its own discretion, perform eligibility redeterminations with the frequency that the State considers to be in the best interest of the SCHIP program.

Comment: One commenter noted that States should carefully consider the effect of not allowing immediate reenrollment of otherwise eligible children in SCHIP. Though the suspected fraud is very unlikely to have been conducted by the child, the commenter noted that it is the child who will suffer.

Another commenter recommended deleting this section because they believed its provisions were not only unnecessary but also might easily be abused. The commenter expressed concern that this rule could be used to justify increased scrutiny of coverage provided to racial and ethnic minorities.

Response: We appreciate this comment. We too are concerned with excluding children from coverage under SCHIP and are committed to ensure that States maintain coverage of children for as long as they are eligible and have deleted this section from the final rule.

17. Verification of Enrollment and Provider Services Received (§ 457.980)

We proposed in § 457.980 that the State must have established systems and procedures for verifying enrollee receipt of provider services. In addition, we specified that the State must establish and maintain systems to distinguish and report enrollee claims for which the State receives enhanced FMAP payments under section 2105 of the Act. We noted that these procedures would serve as a fundamental component of other program integrity activities in this proposed rule, including the fraud detection and investigation efforts discussed under §§ 457.915, 457.925, and 457.930.

Comment: Several commenters noted that the provisions of this section could be difficult to implement in managed care plans and that verification may be burdensome in a capitated system. The commenters requested that we clarify that it would be acceptable if there were a provision in the contract with the health plan to ensure provider services. One commenter expressed concern regarding external verification of provider services received in the managed care market, especially in capitation-based plans. The commenter felt that States should be able to handle

this through the normal provider evaluation and review procedures used by managed care entities.

Response: It is necessary for the effective and efficient administration of any State separate child health insurance program to monitor and verify enrollee receipt of services for which providers have billed or received payment, or that providers have contracted to furnish regardless of the method of reimbursement. Therefore, the provisions of § 457.980(a) apply to States using managed care plans as well as other systems of health insurance and care delivery. Plans participating in SCHIP are accountable to the State for providing services and care to SCHIP participants. States must ensure, when contracting with providers, that beneficiaries are receiving care to which they are entitled and for which States have provided funds.

Comment: We received a couple of comments noting that an error may have occurred in this section as medical providers bill the State but are not billed themselves. This section should read, ''The State must establish methodologies to verify whether beneficiaries have received services for which providers have billed.''

Response: We agree and have changed the text of the regulation.

18. Integrity of Professional Advice to Enrollees (§ 457.985)

To address our concern that enrollees have a right to make informed decisions about their medical care free from any form of financial incentive or conflict of interest involving their provider of care that could directly or indirectly affect the kinds of services or treatment offered, we proposed that States must guarantee in their contracts the protection described in proposed § 457.985(e). We proposed to require that States must include in their contracts for coverage and services, provisions regarding enrollee access to information related to actions that could be subject to appeal in accordance with the ''Medicare+Choice'' regulation at § 422.206, which discusses the protection of enrollee-provider communication and at § 422.208 and § 422.210(a) and (b) which discuss physician incentive limitations. We remain committed to ensuring that appropriate actions are taken to guarantee the protection of enrollee rights regarding their health care services under the Medicare, Medicaid, and SCHIP programs.

Comment: One commenter expressed its support for the requirement to provide enrollee access to information related to actions involving inappropriate arrangements that could be subject to review and appeal. One commenter noted its support for the requirement in § 457.985(e) that States prohibit gag rules and establish principles for disclosure of physician financial arrangements that could affect treatment decisions.

Response: We appreciate the support and have retained these requirements with some modification in the final rule. Section 457.985(e) has now been redesignated as § 457.985(a) and (b).

Comment: One commenter believed that HCFA does not have the authority to apply the M+C physician incentive requirements to separate child health plans.

Response: We disagree with the commenter. Under Section 2101(a) of the Act, the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. A State cannot provide child health assistance in an effective and efficient manner if it allows inappropriate physician incentive plans that have the effect of reducing or limiting health services.

Comment: Several commenters are concerned about the reference in proposed § 457.985(e)(1) prohibiting interference with medical communications between health care professionals and patients. The proposed rule refers to M+C regulations at § 422.206. The commenters would like to include only a specific reference to § 422.206(a) rather than to the whole section. Section 422.206(b) includes a ''conscience protection'' that appears to allow plans to refuse to include in their benefit package any counseling or referral service to which the plan asserts a moral or religious objection. Some commenters noted that there is an explicit statutory provision in the M+C portion of the Balanced Budget Act that deals with conscience-based refusals to provide services and the M+C regulatory provision parallels the statute, but there is no similar statutory requirement in SCHIP. The commenters noted that the regulation also should not reference § 422.206(b) in order to preserve access to health care services and information about them. According to this commenter, a health plan that refuses to provide counseling or referral services impairs access to those services, and typically the services most at risk are reproductive health services provided to women. The commenters further argued that this provision conflicts with the CBRR goal of open communication between health care professionals and patients in all cases, without qualification or exception.

Response: We agree that the regulation should reference only § 422.206(a). The remainder of § 422.206 contains requirements for reporting to HCFA sanctions for Medicare+Choice organizations that are not applicable in a separate child health program. However, not all providers are required to offer all services in the SCHIP benefit packages. If a State contracts with providers that have a moral or religious objection to providing particular services, the State retains the responsibility to assure that enrollees are informed of and have access to all services included as a part of the benefit package consistent with § 457.495.

Comment: One commenter noted that the preamble to the proposed rule (p. 60928), which cross-references § 422.208 of the M+C regulations, appears to apply the physician incentive requirements to separate child health programs. However, § 457.995(d) and § 457.985(e) appear to apply only the disclosure requirements, not the substantial financial risk requirements, to the SCHIP program. This commenter recommended that HCFA clarify this requirement.

Response: A State must guarantee compliance with all of the provisions of § 422.208 (relating to limitations on physician incentive plans) and § 422.210 (relating to disclosure of physician incentive plans) of this chapter as stated in § 457.985.

Comment: One commenter recommended that States should be allowed to provide protections against the gag rule and physician incentives in accordance with their own State law.

Response: While we appreciate State efforts to prohibit gag rules and inappropriate physician incentive plans, it is necessary to require compliance with § 422.208 and § 422.210 of this chapter to ensure nationwide protection of enrollees in separate child health programs consistent with the CBRR.

I. Subpart J—Allowable Waivers: General Provisions

1. Basis, Scope, and Applicability (§ 457.1000)

This subpart interprets and implements the requirements for a waiver under section 2105(c)(2)(B) to permit a State to exceed the 10 percent limit on expenditures as specified in section 2105(c)(2)(A), and for a waiver to permit the purchase of family coverage under section 2105(c)(3) of the Act. This subpart applies to a separate child health program and to a Medicaid expansion program only to the extent

that the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for use of a community-based health delivery system.

Comment: One commenter noted that there appears to be a word missing in § 457.1000(c). The sentence ends with ''seeks a waiver of limitations such claims in light of a community-based health delivery system.'' The commenter believes that ''on'' should be inserted after ''limitations,'' although the meaning is still unclear.

Response: We have corrected § 457.1000(c), as suggested by the commenter, by adding the word ''on''. We have also edited the sentence for clarity. The first part of the sentence now indicates that the requirements of this subpart apply to a separate child health program. The second part of the sentence clarifies that the requirements of this subpart also apply for States that operate Medicaid expansion programs if the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for cost-effective coverage through a community-based health delivery system.

Comment: One commenter suggested that the same time frames for HCFA approval that are proposed for State plan and State plan amendment approvals be included for waivers.

Response: We have amended the regulation text by adding a new § 457.1003 to clarify that we will review the waivers under this subpart as State plan amendments under the time frames as specified in § 457.160. In practice, State proposals for these waivers have been reviewed as part of the initial State plan or amendment and within the 90-day review period permitted under statute. These waivers must be reflected in the State plan and updated accordingly. It should be noted that the 90-day time frame for review does not apply to HCFA review of section 1115 demonstration proposals under this title.

2. Waiver for Cost-Effective Coverage Through a Community-Based Health Delivery System (§ 457.1005)

Section § 457.1005 interprets and implements section 2105(c)(2)(B) of the Act regarding waivers authorized for cost-effective alternatives. In § 457.1005, we proposed requirements for a State wishing to obtain a waiver of the 10 percent limit on expenditures not used for child health assistance in the form of health benefits coverage that meets the requirements of § 457.410. This section also clarifies the extent to which the State will be allowed to exceed the 10 percent limitation on such expenditures in order to provide child health assistance to targeted low-income children under the State plan through cost-effective, community-based health care delivery systems.

To receive payment for cost-effective coverage through a community-based health delivery system under an approved waiver, we proposed that the State must demonstrate that—

- Such coverage meets the coverage requirements of section 2103 of the Act and subpart D of this part; and
- The cost of coverage through the community-based health care delivery system, on an average per child basis, does not exceed the cost of coverage that would otherwise be provided under the State plan.

We noted in the preamble to the proposed rule that a State may define a community-based delivery system to meet the specific needs and resources of a community, as long as it ensures that its community-based delivery system (either through direct provision or referral) can provide all appropriate services to targeted low-income children in accordance with section 2103 of the Act. We also proposed that all community-based providers must comply with all other title XXI provisions.

We proposed that an approved waiver will remain in effect for two years and that a State may reapply three months before the end of the two-year period. We also proposed that, notwithstanding the 10 percent limit on expenditures described in § 457.618, if the cost of coverage of a child under a community-based health delivery system is equal to or less than the cost of coverage of a child under the State plan, the State may use the cost savings for—

- Child health assistance to targeted low-income children and other low-income children other than the required health benefits coverage, health services initiatives, and outreach; or
- Any reasonable costs necessary to administer the State Children's Health Insurance Program.

Comment: One commenter suggested that HCFA adopt the definition of ''health services initiatives'' set forth in the August 6, 1998 letter to State Health Officials. In the letter, the term is defined as ''activities that protect the public health, protect the health of individuals or improve or promote a State's capacity to deliver public health services and/or strengthens resources needed to meet public health goals.'' In addition, the commenter suggested that the preamble make clear that all immigrant children, regardless of their status or date of entry, can participate in, and benefit from, health services initiatives.

Response: We agree with the commenter. We have added the definition of ''health services initiatives'' as set forth in the August 6, 1998 letter to the definitions section of the regulations text at § 457.10. We note that this definition of health services initiatives includes ''other low-income children,'' which can include immigrant children, regardless of their status or date of entry, and children who are eligible for Medicaid but not enrolled. As specified in our January, 14, 1998 letter to State Health Officials, health services initiatives may benefit the health of all low-income children, including but not limited to children eligible to receive services under title XXI. Therefore, health services initiatives such as health education activities, school health programs and direct services (such as newborn hearing and lead testing programs), could be targeted to low-income, immigrant communities.

Comment: One commenter proposed that States be permitted to use title XXI funds under this waiver to pay for primary care services provided by community-based providers to children who are not targeted low-income children eligible for the State's title XXI program, in order to increase access to medically necessary primary care for uninsured SCHIP-eligible children who are not yet enrolled in the State's title XXI program.

Response: States may provide primary care services to children who are not targeted low-income children through a ''health services initiative under the plan for improving the health of children (including targeted low-income children and other low-income children).'' These expenditures would be subject to the 10 percent limit as specified in section 2105(c)(2)(A), except to the extent that the State pays for these services through the use of savings from the waiver for a cost-effective alternative delivery system. In this case, the State could use the savings for primary care services for unenrolled low-income children and those expenditures would not be subject to the 10 percent cap.

Another option for States to consider is using this waiver in conjunction with presumptive eligibility (provisional enrollment). The costs associated with a period of provisional enrollment are benefit costs when the child subsequently is determined eligible for either Medicaid or a separate child health program. However, the costs associated with a period of provisional enrollment for a child who is later

determined ineligible for either Medicaid or a separate child health program are costs that are normally subject to the 10 percent limitation. When services are provided during a period of provisional enrollment to a child who is low-income and whom the State later determines to be ineligible for either Medicaid or a separate child health program, the costs of providing benefits to these low-income, ineligible children could be funded through the use of the waiver for a cost effective alternative delivery system. Again, the benefits provided would have to meet all the requirements of § 457.410.

Comment: One commenter suggested allowing States to set aside a portion of their title XXI allotment for a community-based provider program. The commenter noted 90 percent of the set-aside funds would pay for services to SCHIP eligible children and 10 percent of the set-aside funds would pay for administration.

Response: The Act does not dictate how States set their budgets generally or set budget priorities relating to community-based waiver programs. Section 2105(a) authorizes the Secretary to pay a State from its allotment based upon actual expenditures for child health assistance. The State might be able to make expenditures according to the proportions described above. However, as specified in section 2105(c)(2)(A), the amount of administrative expenditures that a State can claim is directly tied to the amount of expenditures they claim for child health assistance.

Comment: One commenter believed that the language in section § 457.1005(b)(2) is unclear and asked whether the ''State plan'' referred to is the Medicaid State plan or the SCHIP State plan.

Response: The waiver described in proposed § 457.1005(b)(2) is a program waiver under title XXI and, therefore, the State plan referred to in this section is the title XXI State plan, as defined in § 457.10.

Comment: One commenter recommended amending § 457.1005(b)(1) regarding requirements for obtaining a waiver to incorporate a reference to the cost-sharing protections in subpart E and the various beneficiary protections provided in other subparts of the rule and summarized in § 457.995. The commenter was concerned that children receiving care in a community-based health delivery system would not benefit from the consumer protections provided in the regulation, and that States should be not permitted to utilize this waiver as a means of circumventing the protections that are afforded to other SCHIP applicants and enrollees.

Response: As proposed, the regulation text at § 457.1005(b) required States obtaining a waiver for cost-effective coverage through a community-based health delivery system to demonstrate that (1) the coverage meets the coverage requirements of section 2103 of the Act and subpart D of this part; and (2) the cost of such coverage, on an average per child basis, does not exceed the cost of coverage under the State plan. In the preamble to the proposed rule, we stated that, for the purposes of a waiver, all participating community-based providers must comply with all other title XXI provisions. On further consideration, we have clarified the policy under the final regulation. Section 457.1005(b)) now requires that, in providing child health assistance through the waiver, the coverage must meet all the requirements of this part, including subparts D and E. Therefore, the final regulation clarifies that all title XXI protections will apply under a waiver for a community-based delivery system in order to assure that all children receive the same protections regardless of where they receive services.

Comment: One commenter believes that HCFA's example of coverage for a special group, such as children who are homeless or who have special health care needs, does not consider that the care for these children may cost more than the care for the average child. The commenter recommended that HCFA reconsider § 457.1005 and provide options for States to proceed with caring for children with special needs in a manner that allows payment above the cost of providing coverage to the ''average'' child.

Response: Section 2105(c)(2)(B)(ii) of the Act specifies that the cost of coverage through the community-based health care delivery system, on an average per child basis, may not exceed the cost of coverage that would otherwise be provided under the State plan. In an August 6, 1998 letter to State Health Officials, we stated that the amount paid to the community-based delivery system on a Federal fiscal year, per child basis must not be greater than the amount that would otherwise have been paid for that child to receive coverage under title XXI. For example, if the amounts that the State pays health plans under the State plan reflect the risk entailed in providing care to special needs children (because the State risk adjusts its capitation payments, or because the State provides services to these children on a fee-for-service basis), these above-average costs for the special needs children in fact, will be reflected in the cost-effectiveness calculation. Therefore, the cost-effectiveness calculation required under § 457.1005(b)(2) does not preclude the State from adjusting its payments for the care of special needs children to provide for higher payment for such care.

Comment: One commenter applauded HCFA's interpretation of waivers as stated in the proposed rule and agreed with the statement that the purpose of this waiver was to increase health services and not to increase funds for administration.

Response: The preamble of the proposed rule set forth our belief that Congress did not intend that the waiver be used primarily to allow for more administrative spending or spending on outreach services under section 2105(a)(2). While we appreciate the support of the commenter, we also point out that States do retain flexibility regarding the use of any savings obtained as a result of this waiver pursuant to § 457.1005(d).

Comment: A number of commenters recommended that approved waivers should initially remain in effect for three years, to coincide with the time frames at section 2104(e) of the Act for spending the funding allotment for each year, and to provide time to evaluate the waiver's impact and to demonstrate cost-effectiveness. Following the initial approval period, one commenter recommended that the duration be five years, in keeping with the typical duration of 1115 waivers.

Response: We agree with the commenters' suggestion that a 3-year approval period would coincide with statutory time frames for the expenditure of allotments and provide a more adequate period of time in which to determine cost-effectiveness. Therefore, we have revised § 457.1005(c) to provide that the duration of time for which waivers for cost-effective coverage through a community-based health delivery system are approved is three years. We will continue to determine cost-effectiveness upon application and renewal for the waiver. However, we have not accepted the recommendation to extend the waiver period to five years because it is important to assess the cost-effectiveness of community-based health delivery systems on a more frequent basis. We have also revised the regulation at § 457.1005 to indicate that a State may reapply for approval 90 days before the end of the three year period for consistency with the 90 day review period that apply to State plan amendments.

3. Waiver for Purchase of Family Coverage (§ 457.1010)

We proposed that a State must apply for a family coverage waiver when any title XXI funds are used to purchase coverage for adult family members in addition to targeted low-income children. We proposed at § 457.1010 that a waiver for family coverage will be approved by the Secretary if—

- Purchase of family coverage is cost-effective under the standards described in § 457.1015 of this subpart;
- The State does not purchase such coverage if it would otherwise substitute for health insurance coverage that would be provided to such children but for the purchase of family coverage; and
- The coverage for the child otherwise meets the requirements of this part.

We requested comments on whether the benefits specified in title XXI also apply to adults covered by a family coverage waiver. For example, if a State offers ''wraparound coverage'' to bring an employer's benefits up to the title XXI standards, we solicited comments as to whether the State should be required to offer this additional coverage to adults under the family waiver.

We noted that there is no statutory definition of family coverage for the purposes of this subpart and we solicited input from commenters on the definition of ''family'' for purposes of this subpart.

Comment: Many commenters questioned whether States covering parents of SCHIP children through a family coverage waiver must provide the benefits specified in title XXI to the family members who would not otherwise be eligible for SCHIP coverage. These commenters asserted that this decision should be left to State discretion. Commenters did not believe that there is any statutory basis for such a rule. Commenters also indicated that such a requirement would dramatically restrict States' ability to achieve cost-effectiveness in family coverage and would result in a reduction in the number of children that could be insured through the program. Commenters also noted that such a requirement could further complicate the States' administration of benefit and/or cost-sharing upgrades for premium assistance programs because of the difficulty in administering benefit upgrades.

Response: We appreciate the commenters' consideration of this issue, but disagree with the recommendation and rationale because we do not believe it gives weight to the congressional interest in a standard minimum benefit package for all covered individuals. Congress clearly intended that title XXI funds be used to provide a comprehensive benefit package meeting the requirements of section 2103. Children's benefits under a premium assistance program must meet requirements in section 2103, and benefits offered under group health plans typically do not differ for adults and children. In addition, title XXI provides considerable flexibility for States to choose a benchmark package against which they can compare the benefits offered under a group health plan. Therefore, we have decided to require that any health benefits coverage provided under a family coverage waiver must comply with the benefit requirements of § 457.410 and have revised the language at § 457.1010(c) to reflect this change.

Section 2105(c)(3)(A) provides the authority for this policy because it requires that the purchase of family coverage must be cost-effective relative to the amounts that the State would have paid to obtain ''comparable coverage'' for only the targeted low-income children involved. Therefore, this provision clearly contemplates that the coverage offered to non-eligible family members under a family coverage waiver would be comparable to the coverage that would be offered to targeted low-income children. We believe that requiring the family coverage to meet title XXI standards best assures this comparability and is most consistent with the intended use of title XXI funds. However, we have interpreted the statute's use of the term ''comparable'' to permit the coverage of non-SCHIP eligible family members to be based on a different title XXI benchmark than the targeted low-income children's coverage.

While we recognize the cost of family coverage will increase if the State provides wrap-around coverage to adults in addition to the benefits provided by the group health plan, the degree of cost increase is unclear. For example, when the ''wrap-around'' supplemental coverage provided by the State to meet the section 2103 requirements is coverage only for well-baby and well-child services, there would be no additional costs to provide coverage that meets the requirements of section 2103 for adults, because this ''wrap-around'' coverage is not relevant for adults.

Comment: One commenter stated that it is not clear what would be included in a benefits upgrade for adults. For instance, the commenter questioned if there would need to be a prohibition on cost sharing for adult preventive care visits and services to reflect the statutory prohibitions on copayments or cost sharing for well-baby or well-child care. If this were the case, the commenter indicated that the cost of implementing such a provision would obviously be significant.

Response: While States must ensure that health benefits coverage provided to all family members, including adults, meets the requirements of section 2103, not all benefits are relevant to adult enrollees. For instance, while the statute requires the provision of well-baby and well-child care and prohibits cost sharing for these services, these services are not applicable or available to adults. Therefore, States would not be required to provide coverage to adults for these services, and the specific cost-sharing restrictions applicable to these services also would not apply to adults. However, general cost-sharing limitations do apply to covered services for adults and children under the family coverage waiver. For example, some States have expressed interest in providing coverage to families above 150% of the FPL and, for this income level, the cumulative cost-sharing maximum of 5% of family income would apply.

Comment: One commenter suggested that HCFA clarify how wrap-around coverage programs could be designed to make family coverage waivers viable, cost effective and simple to administer for group health plans.

Response: We recognize the challenges faced by States in establishing and operating premium assistance programs. The challenges result from the fact that title XXI primarily was designed for targeted low-income children receiving health benefits coverage through programs operated directly by the State, rather than for families receiving health benefits coverage through group health plans. Nonetheless, it is possible to address these challenges. For example, some States are structuring their premium assistance programs to permit direct billing from providers to the State for services or cost sharing that is not covered by the group health plan. In addition, there is flexibility for States to select from among a variety of benchmark benefit packages, and States should carefully consider this flexibility when designing premium assistance programs. We will continue to share new approaches with States as they are developed.

Comment: Commenters encouraged the use of ''family'' as defined by States, employers, and/or the individual contracting health insurance plans. One

commenter believed that States and the Federal government do not need to, and in fact cannot, develop a standard definition. Commenters noted that family coverage waivers will likely be provided through employer-sponsored plans, where the issue of which family members may be included under the employer plan is regulated by contract with insurers and State insurance law. One commenter is planning to submit a request to subsidize employer-sponsored insurance that involves several premium tiers based on which family members are covered and suggests that the definition of ''family'' include the employee, spouse and children, or employee, and children depending on family composition and the coverage tier selected. Other commenters felt that HCFA should not create a definition of ''family,'' because such a definition could restrict the ability of group health plans or health insurance issuers from defining what constitutes family coverage. One commenter also noted that a more flexible approach would ease administration and maximize the availability of the family coverage waiver option. Another commenter suggested that the definition be left to State discretion and that once HCFA reviews a wide range of proposals, it can revise the regulations to include a definition if necessary.

Response: We have not defined ''family'' for the purposes of this regulation in general and, after considering these comments, we agree with the commenters that one standard definition of ''family'' could unnecessarily restrict States' ability to utilize a family coverage waiver. Therefore, the decision regarding how to define ''family'' is left to States' discretion.

Comment: One commenter urged that the definition of ''family'' include adult pregnant women without other family members. The commenter believes that this expansion of the definition is integral to ensuring that all pregnant women have access in their community to readily available and regularly scheduled obstetric care, beginning in early pregnancy and continuing through the postpartum period.

Response: While we support States' efforts to cover pregnant women, title XXI does not support an expansion of coverage to include pregnant women who are not family members of SCHIP-eligible children. Section 2105(c)(3) permits payment to a State for family coverage under ''a group health plan or health insurance coverage that includes coverage of targeted low-income children.'' The statute requires the State to compare the cost of coverage ''only of the targeted low-income children involved'' with the cost of coverage for the family. A State wishing to cover a pregnant woman who is not a family member of a targeted low-income child would not be able to perform the required cost-effectiveness test. Therefore, a pregnant woman can be covered through a family coverage waiver only to the extent that a targeted low-income child in her family is eligible for SCHIP coverage.

Comment: A commenter noted that in the preamble to the proposed rule, we stated that States must apply for a family coverage waiver when any title XXI funds are used to purchase coverage for adult family members in addition to targeted low-income children. We also noted that States may purchase coverage for children through premium assistance programs using employer-sponsored insurance without a family coverage waiver when the costs of such children are identifiable. One commenter was concerned that the premium tier structures available to most employers do not permit the costs of children to be identified. The commenter noted that employers offer only two coverage tiers, employee-only and family coverage, which does not permit this kind of determination, because other family members, such as spouses, also may be covered under the family coverage tier. The commenter asserted that the options permitted in the proposed rule for determining the cost of children under employer-sponsored coverage will mean that most States seeking to cover a significant number of uninsured children under a premium assistance program will need to obtain a family coverage waiver.

Because States may wish to utilize employer-sponsored insurance without subsidizing coverage for the adults in the family, the commenter suggested an alternative method for determining the cost of targeted low-income children covered through employer-sponsored coverage. The commenter proposed that States be permitted to pay a proportion or percentage of the cost of employer-sponsored family coverage without obtaining a family coverage waiver, as long as the portion the State pays is based on a reasonable actuarial estimate of what proportion of the cost of family coverage is attributable to the children, and as long as it meets the cost-effectiveness test.

The commenter suggested that the actuarial determination of the proportion to be paid could be made once a year, based on typical group health coverage plan available in the State, and the percentage could then be applied to the actual premium for family coverage under the specific employer's plan.

Response: We have reconsidered the requirement in the preamble to the NPRM that a family coverage waiver is needed when any title XXI funds are used to provide coverage for adult members of the family. We will not require States to obtain a family coverage waiver in cases where the employee's premium is not subsidized and there is no intention on the part of the State to cover family members other than targeted low-income children. We also agree that the suggestion offered by the commenter appears to offer another possible option for States to identify the costs of enrolling only the eligible child or children in the family into a premium assistance program, and thereby enroll the children without obtaining a family coverage waiver. As described in the proposed rule, child-only costs can be identified when a State is purchasing a child-only policy, or in markets in which carriers offer policies with a sufficient number of premium tiers to identify the costs of the SCHIP-eligible child or children. Such tiers might include an employee-only premium tier, and an employee-plus-children premium tier, such that the former can be subtracted from the latter to determine the cost of the child or children. However, as the commenter points out, these premium tier structures may not be common or uniformly available in most States.

In a more typical group health insurance market that offers coverage tiers for employee-only or family coverage, the employee contribution amounts for employee-only and for family coverage are known. The difference between the two is the cost for dependent coverage. Again, if title XXI only subsidizes the difference between employee-only and family coverage, a family coverage waiver is not needed as long as there is no intention to cover non-SCHIP eligible family members. However, as an alternate approach, the State could decide to allocate the cost for dependent coverage between the spouse and children on a reasonable actuarial basis and a family coverage waiver would not be required if the State then pays only that portion allocated to coverage of the targeted low-income child or children. An actuary familiar with the State's group health market could produce an estimate of the cost of one adult relative to the cost for one child under a group health plan. This ratio could then be applied to the family composition to determine what portion of the premium pays for the spouse's coverage and what

portion pays for the children's coverage. The State would then pay only that portion attributable to the child or children.

We note, however, that this method may be difficult for States to implement in practice given the need to obtain sufficient data to perform the necessary actuarial estimates. In addition, the subsidy amount determined under this method does not cover the family's full premium cost, which may discourage some families from enrolling. For these reasons, calculating the difference between employee-only and family coverage costs may be a preferable alternative to obtaining actuarial estimates of the costs of only the targeted low-income children for many States. We also note that when a State subsidizes family coverage, but is covering only targeted low-income children (that is, no payment is being made for the employee portion of the premium, and there is no intention to cover family members other than the targeted low-income children and the costs do not exceed the cost-effective amount), the requirements of this part apply to only the targeted low-income children. We reiterate that family coverage waivers are subject to the same 90-day review period as any other title XXI State plan amendment and need not be unduly burdensome to obtain.

In order to assist States in designing premium assistance programs to cover only targeted low-income children using employer sponsored insurance, we will work with States on their specific proposals to develop mechanisms for identifying the cost of covering the targeted low-income children using reasonable methods, for the purposes of determining cost-effectiveness.

Comment: Several commenters indicated that family coverage waivers will be challenging for States to implement. One commenter expressed concern that the standards for family coverage waivers are impossible to meet and should be made easier to accomplish via a statutory change. Another commenter supported States' interest in developing programs to provide coverage to whole families and urged HCFA to provide more support and technical assistance and to grant more family coverage waivers.

Response: We are committed to sharing best practices and providing guidance to States designing and implementing family coverage waivers and premium assistance programs. To date, three States have received approval for family coverage waivers. As States gain more experience with their premium assistance programs and their family coverage waivers, we will work to disseminate information about the challenges and successes of these programs.

Comment: A number of commenters were concerned that the proposed regulations are too restrictive regarding when a family coverage waiver is needed. Some noted that, while Congress intended to expand coverage to children, recent research suggests that expanding parents' access to health care coverage also increases children's enrollment, as parents are more likely to apply for and enroll their children in a health insurance program if the whole family is covered by the same plan. They encouraged HCFA to permit States to experiment with both title XIX and title XXI funds to cover parents as an effective strategy to increase enrollment levels of children. They also noted that most States have not spent a significant portion of their title XXI allotments, and may be able to expand coverage further if more flexibility is granted for enrolling parents under title XXI.

Response: We recognize the link between children's enrollment and parental access to SCHIP coverage. We have provided flexibility on this as permitted by the statute. Section 2105(c)(3) sets forth certain requirements relating the coverage of families through a family coverage waiver, and § 457.1010 of this regulation implements that section. However, we will continue to work with States that wish to design and implement programs under a family coverage waiver to help facilitate the enrollment of parents of SCHIP-eligible children in a manner consistent with title XXI.

Comment: One commenter stated that the proposed rule indicates that the community-based waiver applies to Medicaid expansion programs, but the family coverage waiver does not. It is the commenter's opinion that family coverage waivers should be allowed in Medicaid expansion programs.

Response: Family coverage waivers are required whenever States are funding coverage for any non-SCHIP eligible family members with title XXI funds under a separate child health program. Under Medicaid, States are able to purchase employer-sponsored coverage for regular Medicaid and Medicaid expansion enrollees under section 1906 of the Act, which permits States to pay premiums, deductibles, and coinsurance on behalf of Medicaid beneficiaries eligible for enrollment in employer-based group health plans when it is cost-effective to do so. The only exception to this distinction between family coverage in Medicaid expansions and separate child health programs is within the context of our authority under section 1115 of the Act. Section 1115 demonstrations are not subject to regular Medicaid rules when those rules are modified under the Secretary's authority to grant certain waivers, to provide federal funds for costs that would not otherwise be matchable and to impose special terms and conditions for such demonstrations. In all cases, we are committed to working with States interested in using either funding source, either separately, or in conjunction with each other. As mentioned previously, a family coverage waiver is not needed when the coverage of adult family members is only incidental.

Comment: Several commenters supported coverage of adult family members under family coverage waivers. One commenter supported State flexibility to cover family members but believed that before granting a family coverage waiver, HCFA should ensure that States have utilized their options for expanding health coverage to lower-income adults in non-title XXI funded programs. The commenter notes that HCFA and ACF, in their publication ''Supporting Families in Transition,'' indicated that before expanding coverage under title XXI, States will need to implement a Medicaid expansion under section 1931 of the Act to avoid an anomalous result in which higher income families are covered under SCHIP, while parents of lower-income children lack coverage. Another commenter suggested that HCFA encourage States to apply for Medicaid waivers to expand insurance coverage to adult pregnant women and to facilitate the more rapid enrollment of their infants.

Response: We agree that States' ability to use Medicaid rules to expand coverage to other family members is an important option, and we have been working with States to clarify the flexibility that exists to do this. Under Medicaid, States may purchase family coverage through employer-sponsored coverage under section 1906 of the Act, which permits States to pay enrollee premiums in employers' group health plans when it is cost-effective to obtain coverage for Medicaid-eligible individuals (deductibles, coinsurance and other cost sharing for ineligible family members may not be paid as medical assistance).

In addition, States may submit proposals for demonstrations under section 1115 of the Act to expand coverage to parents of children covered under SCHIP. HCFA released guidance on July 31, 2000 regarding parameters for consideration of such proposals.

Comment: Several commenters proposed that States should meet prerequisites before receiving approval for family coverage waivers. Some commenters proposed that States must eliminate the asset test under Medicaid and SCHIP and adopt simplified application, enrollment and redetermination procedures for children. Other commenters suggested that States should expand coverage for children with family income up to at least 200 percent of FPL (or 50 percentage points above the State's Medicaid applicable income threshold) throughout the areas of the State; ensure that all eligible children are promptly enrolled into a State's title XXI program without being subject to a waiting list; and, if the State operates a separate child health program, adopt a joint Medicaid/SCHIP application and assure that the same or directly comparable application, enrollment and redetermination procedure is used for children under Medicaid and the separate State program. Another commenter proposed that States should first be required to ensure that there is no lessening of SCHIP benefits or increase in cost sharing associated with a waiver using this method of calculating cost-effectiveness.

Response: While we support all of these goals, title XXI provides no statutory authority for requiring States to meet these goals prior to the approval of a family coverage waiver. We have been working with States to clarify Federal law and to provide technical assistance regarding the implementation of such policies in order to support States' efforts to undertake activities that will expand and simplify eligibility, increase the number of children who enroll in States' programs, and to make the enrollment and redetermination processes less burdensome on States, applicants and enrollees.

4. Cost-Effectiveness (§ 457.1015)

This section defines cost-effectiveness and describes the procedures for establishing cost-effectiveness for the purpose of a family coverage waiver.

We proposed that cost-effectiveness means that the cost of purchasing family coverage under a group health plan or health insurance coverage that includes coverage for targeted low-income children is equal to or less than the State's cost of obtaining such coverage only for the eligible targeted low-income child or children involved. Stated more simply, cost-effectiveness for the family coverage waiver means that the cost of providing family coverage (including coverage for the parents) is equal to or less than the cost of covering only the SCHIP-eligible children.

We proposed that a State may demonstrate cost-effectiveness by comparing the cost of family coverage that meets the requirements of §§ 457.1010 and 457.1015 of this subpart, to the cost of coverage only for the targeted low-income child or children under the health benefits packages offered by the State under the State plan for which the child is eligible. Alternatively, we proposed that the State may compare the cost of family coverage to any child-only health benefits package that meets the requirements of § 457.410, even if the State does not offer it under the State plan. We stated that we would examine other alternatives and we invited comment on additional methods for demonstrating cost-effectiveness. We set forth an illustration of cost comparison in the proposed rule.

We proposed that the State may demonstrate the cost-effectiveness of family coverage by applying the cost of family coverage for individual families assessed on a case-by-case basis, or for family coverage in the aggregate. We noted that if a State chooses to apply the cost-effectiveness test on a case-by-case basis, the State must compare the cost of coverage for each family to the cost of coverage for only the child or children in the family under SCHIP. We further explained that if a State chooses to apply the cost-effectiveness test in the aggregate, the State must provide an estimate of the projected total costs of the family coverage program compared to the cost the State would have incurred for covering just the children in those families under the publicly-available SCHIP plan. If the State chooses to assess the cost of family coverage in the aggregate, we also proposed that, on an annual basis, the State must compare the total actual cost of covering all families for whom the State has purchased family coverage to the cost the State would have incurred covering just the children in those families under the publicly-available SCHIP plan. If the aggregate cost of family coverage was less than the cost to cover the children under the publicly available program, then the family coverage would be considered cost-effective. If the State determines through its annual assessment of cost-effectiveness that family coverage is not cost-effective in the aggregate, we proposed that the State must begin to apply the cost-effectiveness test on a case-by-case basis.

Comment: Many commenters indicated that, given the two-year length of approved waivers, the cost-effectiveness assessment should be done for the life of the waiver.

Response: Section 457.1015 addresses cost-effectiveness for family coverage waivers only, and does not address the cost-effectiveness of waivers for a community-based delivery system. Cost-effectiveness of waivers for a community-based delivery system is determined each time a State applies for or renews its waiver. As stated earlier, we have agreed to extend the period of time for which these waivers are approved from two years to three years.

Family coverage waivers are part of the State plan and are approved for an open-ended period of time after an initial demonstration of cost-effectiveness. However, we will continue to require a State to demonstrate the cost-effectiveness of the family coverage waiver on an annual basis, whether done on a case-by case or aggregate basis, consistent with § 457.1015(d). Because we have little information about the costs associated with family coverage waivers, we want to assure that States' premium assistance programs are being administered in the most cost-effective manner possible, and to be able to obtain results so as to share best practices with other States.

We have reconsidered the proposed provision that would have permitted States to conduct its cost comparison against any child-only policy even if it is not offered under the State plan. The revised language requires that the cost comparison be done relative to the State's actual costs under the State plan in order to assure coverage is provided in the most cost effective manner.

Comment: Several commenters wrote to express support of the rule as written with regard to the cost-effectiveness test. One commenter supported permitting States to perform retrospective cost-effectiveness evaluations but suggested that the cost-effectiveness comparisons should be clarified. Specifically, the commenter indicated that the first example (64 FR 60932) omits any costs for the supplemental coverage that will likely need to be provided and included in the cost-effectiveness test because employer plans may not always cover some services that must be covered under title XXI or exempt well-baby and well-child care from cost sharing.

Response: Although the example in the NPRM did not include the cost of supplemental benefits, the cost of supplemental benefits must be reflected in States' cost-effectiveness analyses. For example, assume the cost to cover two targeted low-income children under the State plan is $200 per month and the cost to cover the family in the employer

plan is $120 per month. The State also provides supplemental coverage for benefits and cost sharing that costs $40 per month per family. This $40 would be added to the $120 for a total of $160 which is still cost-effective in comparison to the $200 that would have been paid under the State plan for only the children. We have also revised the provision at § 457.1015 to indicate that cost-effective means that the cost of purchasing family coverage that includes coverage for targeted low-income children is equal to or less than the State's cost of obtaining coverage under the plan only for the targeted low-income children involved. We have eliminated the specific reference to the cost paid under a group health plan or health insurance coverage in order to clarify that all costs associated with providing family coverage, including any supplemental coverage, must be considered when determining cost-effectiveness.

Comment: Some commenters believed that because the Department has not developed standards or guidance regarding budget neutrality, State determinations of cost-effectiveness must be accepted and reasonable waivers and family coverage variances should be approved in a timely fashion.

Response: We have clarified the requirements for determining cost-effectiveness under the waiver for cost-effective coverage through a community based delivery system and the waiver for family coverage in both the NPRM and this final rule. Budget neutrality is a relevant consideration with respect to section 1115 demonstration projects, but not with respect to waivers discussed under subpart J. We are committed to working with States interested in designing and implementing the waivers under subpart J to find the best way possible to comply with these regulations and effectively implement their programs.

J. Subpart K—Applicant and Enrollee Protections

In response to public comment, in this final rule, we relocated certain provisions involving applicant and enrollee protections to this new subpart K, ''Applicant and Enrollee Protections.'' Specifically, we moved to this subpart certain provisions of proposed § 457.902, which set forth definitions applicable to enrollee protections, proposed § 457.985, which set forth requirements relating to grievances and appeals, and proposed § 457.990, which set forth requirements for privacy protections. Public comments received on the relocated proposed provisions and changes made to them are discussed below.

To eliminate inconsistency and potential confusion, and in response to public comment, we decided to remove from the regulation text proposed at § 457.995, which provided an overview of the enrollee rights provided in this part. Instead, we provide an overview of the enrollee protections contained throughout the part in the preamble to this final regulation. We respond below to the general comments on proposed § 457.995, as well as to any general comments relating to the Consumer Bill of Rights and Responsibilities (CBRR). To the extent that a comment on proposed § 457.995 relates to a specific enrollee protection provision cross-referenced in the proposed overview section, but located elsewhere than subpart I of the proposed regulation, we responded to that comment earlier in this final rule in conjunction with comments and responses relating to that specific provision.

The most significant changes reflected in this subpart were made to the proposed ''grievance and appeal'' provisions at § 457.985. Given the lack of clarity regarding the use of the terms ''grievances'' and ''appeals,'' as noted by some of the commenters, we removed these terms from the final regulation. We opted instead, as we make clear in our responses to comments, to refer to the procedural protections required under this regulation as the ''review process.'' We also note that in clarifying the scope and type of matters subject to review, we narrowed the range of matters subject to review from those defined in the proposed regulation. The minimum requirements for a review process identified in this regulation will apply only to separate child health programs, and States retain a significant amount of flexibility in designing their processes.

In this final regulation, a State is required to include in its State plan a description of the State's review processes and, pursuant to § 457.120, to offer the public the opportunity to provide input into the design of the review process. We also clarify that matters involving eligibility and enrollment, on the one hand, and health services, on the other, are subject to somewhat different review requirements. Core elements for a review process applicable to reviews of both types of matters; States may adopt their own policies and procedures for reviews that address these core elements. Such policies and procedures must ensure that—(a) Reviews are conducted by an impartial person or entity in accordance with § 457.1150; (b) review decisions are timely in accordance with § 457.1160; (c) review decisions are written; and (d) applicants and enrollees have an opportunity to—(1) represent themselves or have representatives of their choosing in the review process; (2) timely review their files and other applicable information relevant to the review of the decision; (3) fully participate in the review process, whether the review is conducted in person or in writing, including by presenting supplemental information during the review process; and (4) receive continued enrollment in accordance with § 457.1170. Under the provisions of this final rule, a State could use State employees, including State hearing officers, or contractors to conduct the reviews, reviews could be conducted in person, by phone or based on the relevant documents, and a State could choose to use the same general process or different processes for reviews of eligibility and enrollment decisions and health services decisions.

With respect to enrollment matters, States must provide an applicant or enrollee with an opportunity for review of: (1) A denial of eligibility; (2) a failure to make a timely determination of eligibility; or (3) a suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. States are not required to provide an opportunity for review of these matters if the sole basis for the decision is a change in the State plan or a change in Federal or State law (requiring an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances). For example, if a State amends its plan to eliminate all speech therapy services, a review would not be required if an individual appeals the denial of speech therapy. The final rules also establish that States must complete the review within a reasonable amount of time and that the process must be conducted in an impartial manner by a person or entity (*e.g.* a contractor) who has not been directly involved with the matter under review. For matters related to termination or suspension of enrollment, including a disenrollment for failure to pay cost sharing, the rules require that a State ensure the opportunity for continued enrollment pending the completion of the review.

As to adverse health services matters, a State must provide access to external review of decisions to delay, deny, reduce, suspend, or terminate services, in whole or in part, including a

determination about the type or level of services; or of a failure to approve, furnish, or provide payment for health services in a timely manner. The external review must be conducted in an impartial and independent manner, by the State or a contractor other than the contractor responsible for the matter subject to external review. All reviews must be completed in accordance with the medical needs of the patient. The rules establish an overall 90-day time frame for external review, including any internal review that may be available. The rules also establish a 72-hour expedited time frame in the case where operating under the standard time frames could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. In such situations, the enrollee has access to internal and external review, then each level of review may take no more than 72 hours. If the enrollee's physician determines the review should be expedited then it must be conducted accordingly, both for internal (if applicable) and external review.

In addition, we clarify the notice requirements at § 457.1180, and require a State in § 457.110(b)(6) to make available to potential applicants, and provide to applicants and enrollees information about the review processes that are available to applicants and enrollees. The rules also require that States ensure that enrollees and applicants are provided timely written notice of any determinations required to be subject to review under § 457.1130 that includes the reasons for the determination; an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, and the manner in which a review can be requested; and the circumstances under which enrollment may continue pending review. Section § 457.340(d) requires that in the case of a suspension or termination of eligibility, the State must provide sufficient notice to enable the child's parent or caretaker to take any appropriate actions that may be required to allow coverage to continue without interruption.

We provide States with flexibility under § 457.1190 related to coverage provided through premium assistance programs to assure that all SCHIP eligible children have access to these enrollee protections, while recognizing States' reduced ability, or in some cases inability, to affect group health plan review procedures. This section provides that in States choosing to offer premium assistance programs, if the group health plan(s) through which coverage is provided are not found to meet the review requirements of §§ 457.1130(b), 457.1140, 457.1150(b), 457.1160(b), and 457.1180, the State must give applicants and enrollees the option to obtain health benefits coverage other than coverage through that group health plan. The State must provide this option at initial enrollment and at each redetermination of eligibility.

1. Overview of Enrollee Rights (Proposed § 457.995)

In the proposed rule, we set forth in § 457.995 an overview of certain enrollee rights that we provided throughout the proposed rule. In determining the scope of consumer protections to apply to separate child health programs, we considered the Secretary's statutory authority under title XXI and, within that authority, we attempted to balance the goal of ensuring consumer rights for SCHIP-eligible children with the need to afford States flexibility to design their separate child health programs. In this spirit, we proposed the enrollee protections listed in proposed § 457.995 for enrollees in separate child health programs, and we also solicited public comments on how best to balance these interests in this regulation.

As noted above, while we removed proposed § 457.995 from the regulation text in response to public comment, we respond to the general comments on proposed § 457.995 below. We respond to comments on the specific provisions cross-referenced in the § 457.995 overview and contained in other subparts along with the responses to other comments on those cross-referenced provisions. For example, proposed § 457.995 contains a cross-reference to § 457.110 and the comments to proposed § 457.995 also included comments on § 457.110. We respond to the latter set of comments on § 457.110 together with the other comments on § 457.110. Below you will find our responses to the general comments on § 457.995. Following our responses to general comments on this section is an overview of the enrollee protections provided in this final regulation.

Comment: One commenter suggested that HCFA either (1) consolidate all of the sections that relate to enrollee protections in one or two sections; or (2) leave the protections in different parts of the proposed rule, ensure that the protections are consistent with the CBRR, and provide a summary of the protections in the preamble only. While this commenter strongly supported HCFA's attempt to address the CBRR, the commenter believed that the proposed rule does not incorporate the rights and requirements in a logical fashion. They noted that § 459.995 merely summarized requirements found in other sections of the rule, so it seemed redundant and, at times, inconsistent. According to this commenter, for example, § 457.110(b) provided that information provided to enrollees must be ''accurate'' and ''easily understood'' and that the information must be ''made available to applicants and enrollees in a timely manner.'' Proposed § 457.995(a)(4), however, provided that ''information must be accurate and easily understood and provide assistance to families in making informed health care decisions.'' These two provisions addressed similar issues but included slightly different requirements, and this commenter argued that these inconsistencies are difficult to reconcile and therefore could result in inappropriate interpretations by States, courts, and enrollees. This commenter generally requested that HCFA reconcile the substantive requirements in other sections of the regulations with the requirements in § 457.995(a) and (b).

The commenter also recommended that the provision relating to ''assistance'' include a reference to ''application assistance'' in § 457.361(a) and to translation services. The same commenter suggested that HCFA correct the citations referenced in § 457.995(a)(3). A different commenter noted that there is no § 457.735(c), and the reference in § 457.995(b) to § 457.735(c) should instead be to § 457.735(b). One commenter also suggested that HCFA divide § 457.995(c) regarding access to emergency services into two separate sections: ''access'' and ''cost sharing for emergency services.''

Response: We agree with the comments about the inconsistency between § 457.995 and certain other substantive sections of the regulation. As noted above, to avoid confusion, we removed proposed § 457.995 from the regulation text and provide an overview in the preamble of the enrollee protections provided throughout the regulation. As for the comments about the cross-references and the need to address certain issues separately, we made every effort to ensure that the cross-references in the final regulation are correct and that issues are adequately addressed in the regulation provisions and explained in the overview now provided in the preamble.

Comment: Many commenters expressed support for HCFA's decision to incorporate the CBRR provisions in the proposed regulations. One

commenter specifically noted that the rights to apply for assistance, to have applications processed in a timely manner, to be informed about benefits, participating providers and coverage decisions, and to have access to a fair process to resolve disputes are basic consumer protections that are critical to ensuring that the program's promise of health care coverage becomes a reality. Another commenter supported the recognition of consumer protections relating to emergency services, participation in treatment decisions, and respect and nondiscrimination. One commenter expressed support for HCFA offering States a good deal of flexibility in the application of these requirements.

Response: We appreciate the support expressed by the commenters.

Comment: Several commenters believed that HCFA exceeded its statutory authority in applying the CBRR to title XXI regulations. Several commenters recommended deleting section § 457.995 because, in their view, there is no basis for implementation of the CBRR in title XXI and, in many cases, States already have Patient Bill of Rights laws. One commenter noted that children in Medicaid expansion programs will be covered under consumer protections available in Medicaid, while children in separate child health programs will be covered under State consumer protection laws. One commenter suggested that, where a conflict exists, or similar requirements are imposed by State law, State law should prevail. This same commenter urged HCFA to consider a ''substantial compliance'' process in these instances. Several other commenters added that they support protecting health care consumers, but that, in their view, requiring the States to implement specific consumer protections for SCHIP could have additional fiscal and administrative impact on their programs.

Response: In establishing the applicant and enrollee protections, we did not simply import the CBRR. We considered our statutory authority, the nature and scope of State laws that might apply to separate child health programs, the need for minimum consumer protection standards, and the States' authority under title XXI to design their own program consistent with the requirements of Federal law. There is statutory authority under title XXI for each enrollee protection included within this final regulation as outlined in the overview and set forth in this part. We describe the statutory authority for each of the enrollee protections in the preamble to each proposed section containing an enrollee protection, in the ''Basis, Scope, and Applicability'' regulation section of each subpart containing one of the enrollee protections, and often in our responses to the specific comments on the sections or subparts of the proposed rule containing the enrollee protections. While we removed § 457.995 from the regulation text, this was done for clarity and to promote consistency, and does not reflect any change in our position regarding the statutory authority for the cited enrollee protections.

States are required to ensure that enrollees in separate child health programs are afforded the minimum consumer protections set forth in this regulation. These minimum protections set a framework within which States may design their procedures consistent with applicable State laws, and we believe it will not be difficult to ascertain whether Federal or State law prevails. If a contractor serving enrollees in a separate child health program is subject to State consumer protection law that is more prescriptive in the areas addressed in this regulation, then in complying with State law, the contractor will comply with this Federal regulation as well. For example, if a State law requires the completion of its review processes for certain health services decisions within a shorter time frame than does this regulation, the State will comply with both Federal and State law when it complies with the shorter State-required time frame. On the other hand, if the Federal time frame requirement is shorter, the Federal requirement will prevail. We have set specific time frames in only a limited number of circumstances to establish the outer boundaries of an efficient and effective system that accomplishes the purpose of the Act. Given the scope of the flexibility afforded States under these rules, we expect that the instances where these Federal rules will impose more stringent standards than those imposed by State law, in those States with an applicable State law, will be limited. In addition, the processes by which certain disputes are resolved are left completely to States' discretion; in such cases, State rules will control. By requiring that a State delineate review procedures in its State plan, we expect the State plan development process, including public notice and comment, will promote State-specific approaches to designing review procedures that reflect local issues and accommodate the State's administrative structure, while ensuring minimum protections to applicants and enrollees.

We will work with States to resolve any questions that might arise in a particular State. No additional compliance process will be instituted beyond that which is already established in subpart B of part 457 under the authority of section 2106(d)(2) of the Act, which requires States to comply with the requirements under title XXI and empowers HCFA to withhold funds in the case of substantial noncompliance with such requirements.

As for the fiscal impact of these requirements, we do not believe that the costs need to be large relative to the cost of services provided to enrollees. The protection of enrollee rights is a critical component of program costs for the provision of child health assistance. States retain broad flexibility to design and implement efficient and effective review processes. Because these regulations do not prescribe any particular review process, States have the flexibility to rely on other already established State review processes for the purpose of resolving disputes that arise in the context of their separate child health programs.

Comment: One commenter noted that, in the preamble to the proposed regulation, we cited a Presidential directive on the CBRR as justification for imposing requirements on State child health plans. This commenter believes that this justification was not sufficient because the proposal conflicted with Executive Order 13132 provisions limiting federal agencies from unnecessarily limiting State flexibility. This commenter expressed the view that HCFA lacks authority to impose the CBRR upon the States to the extent that the CBRR contradicts Congress' unambiguous intent when enacting title XXI and to the extent that it conflicts with E.O. 13132. In this commenter's view, title XXI was designed to provide flexibility to the States in creating and implementing SCHIP programs, and requires the States to describe to HCFA the different aspects of the State plans with minimal restrictions. This commenter argued that, although Congress adopted a general approach intended to allow States to design and experiment with their programs, HCFA has applied the CBRR to remove States' flexibility, and has brought the CBRR to bear most heavily on States that exercised that flexibility. This commenter asserted that a State should be able to tailor its own program to achieve the broad goals of the CBRR and should be able to do so by innovative means tailored to the needs of its population. In this commenter's opinion, we could ''cure'' the regulation (1) by eliminating proposed §§ 457.985, 457.990 and 457.995; and, more importantly, (2) by

evaluating each separate program on its own terms.

Response: As noted above, there is statutory authority for each applicant and enrollee protection outlined in the overview and set forth in this part. In considering how to develop applicant and enrollee protections for this regulation generally, we attempted to balance the important goal of ensuring consumer rights for the SCHIP-eligible population with the flexibility afforded States under title XXI to design their separate child health programs, and we have also considered the value of enrollee feedback through the review process in ensuring compliance with program requirements. In all instances, we have based our regulations on the provisions of title XXI. In our view, the final regulations comply with title XXI and are consistent with the CBRR and E.O. 13132. The regulations establish minimum standards and offer States the opportunity to design their own systems and procedures consistent with these standards. This final regulation does not require a uniform system for providing basic protections to children and their families but rather recognizes and permits significant State-by-State variation.

Comment: One State expressed concern that the level of detail of the CBRR provisions in the proposed regulation severely limits States' flexibility in contracting and hampers their ability to adjust contract provisions that are not working well. Another commenter stated that HMOs and insurers would be less likely to participate in SCHIP if they have to implement both the State requirements and the requirements within the proposed rule, which may have conflicting language.

Response: We appreciate the commenters' concerns and have taken the comments into account in these final regulations. In order to provide all applicants and enrollees the protections established by these regulations pursuant to title XXI, it is essential for contracts to reflect the provisions in this final regulation. However, while we included several important protections within this regulation, we also omitted other details and protections provided by the CBRR, to allow States to design their own review procedures and to minimize any conflict with applicable State law. States have flexibility in the design and implementation of applicant and enrollee protections and we are available to provide technical assistance to States and to facilitate discussions among States as they develop or revise contracts so that they comply with the final regulations. We will also share information about successful State practices among the other States.

Comment: One commenter recommended that HCFA use national standards in applying the principles outlined in the CBRR, such as the Standards on Utilization Management and Member Rights and Responsibilities of the National Committee for Quality Assurance (NCQA). This commenter believed that a standardized system reduces administrative complexity and cost and is more likely to benefit all managed care enrollees. The commenter recommended that the final rule include provisions that allow States to adopt other systems that comport with the BBA and HCFA's Quality Improvement Standards for Managed Care objectives (QISMC), subject to review and approval by HCFA.

Response: We appreciate the recommendation for using the standards issued by NCQA, a private organization that accredits managed care entities, on Utilization Management and Members Rights and Responsibilities. We encourage States to explore such models as a means to develop and implement high quality processes that protect applicant and enrollee rights in a comprehensive manner. While there are advantages to a standardized system, we considered such models and opted to develop minimum standards and permit States the ability to adopt or vary from such models, as long as the standards established by the final regulations are met.

Comment: Several commenters suggested that a provision be added to § 457.995 to require States to include in their managed care contracts provisions that implement all relevant State laws in the area of managed care consumer protections. One of these commenters believed that State law protections should apply to State contracts with entities arranging for the delivery of care that might not be licensed insurance carriers.

Response: While we recognize the importance of the managed care consumer protections contained in many States' laws, we do not require that the contracts comply with State consumer protection laws applicable to certain health plans. The inclusion of such protections in SCHIP contracts is a matter of State law. To the extent that a managed care entity or entity that contracts with a State in connection with its SCHIP program is subject to State insurance or business laws, the entity would be required to comply with applicable State law. We encourage States to include in their contracts with health plans, or other organizations, the applicable patient protections required under State law to the extent they do not conflict with the standards in this regulation.

Comment: One commenter suggested that this overview section also list enrollees' rights to linguistic access to services. This commenter recommended that the preamble explain these rights and provide examples, such as providing bilingual workers and linguistically appropriate materials that include recommendations on how States and contracted entities can comply. Another commenter requested that cultural competency and linguistic accessibility requirements be incorporated throughout the provisions on information, choice of providers and plans, access to emergency services, participation in treatment decisions, respect and nondiscrimination, and grievances and appeals.

Response: We addressed these comments in subpart A along with other comments on §§ 457.110 and 457.130 involving compliance with civil rights requirements and the linguistic appropriateness of information provided to enrollees.

Overview of Applicant and Enrollee Protections in Final Regulation

In this final rule, we require States to provide certain protections for applicants and enrollees in separate child health programs. Outlined below are the protections afforded under this regulation.

- Information Disclosure

Section 457.110 provides that States must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants, and enrollees and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. In addition, this section that families be provided information on physician incentive plans as required by the final regulation at § 457.985. We also require, at § 457.65(b), that a State must submit a State plan amendment if it intends to eliminate or restrict eligibility or benefits, and that the State certify that it has provided prior public notice of the proposed change in a form and manner provided under applicable State law, and that public notice occurred before the requested effective date of the change.

Under § 457.350(g), we require States to enable families whose children may be eligible for Medicaid to make informed decisions about applying for Medicaid or completing the Medicaid application process by providing information in writing on the Medicaid program, including the benefits covered

and restrictions on cost sharing. Such information must also advise families of the effect on eligibility for a separate child health program of neither applying for Medicaid nor completing the Medicaid application process. Finally, § 457.525 provides that the State must make a public schedule available that contains the following information: current cost-sharing charges; enrollee groups subject to the charges; cumulative cost-sharing maximums; mechanisms for making payments for required charges; and the consequences for an applicant or enrollee who does not pay a charge, including the disenrollment protections required in § 457.570.

• Choice of Providers and Plans

The rules provide enrollees with certain protections regarding choice of providers and plans through §§ 457.110 and 457.495. Section 457.110 provides that the State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants, and enrollees, and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. Section 457.495 provides that, in its State plan, a State must describe its methods for assuring: (1) The quality and appropriateness of care provided under the plan particularly with respect to well-baby, well-child and adolescent care, and immunizations; (2) access to covered services, including emergency services as defined at § 457.10; (3) and appropriate and timely procedures to monitor and treat enrollees with chronic, complex, or serious medical conditions, including access to specialists experienced in treating the specific medical condition; and (4) that decisions related to the prior authorization of health services are completed in accordance with the medical needs of the patient, within 14 days of the receipt of a request for services.

• Access to Emergency Services

Sections §§ 457.410(b), 457.515(f), 457.555(d), and 457.495 address the right to access emergency services. Section § 457.10 defines ''emergency medical condition'' and ''emergency services'' using the ''prudent layperson'' standard recommended by the President's Advisory Commission and adopted by many States in their consumer protection laws. Section 457.410(b) requires that regardless of the type of health benefits coverage offered under a State's plan, the State must provide coverage for emergency services as defined in § 457.10.

Under § 457.555(d), for targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State may charge up to twice the charge for non-institutional services, up to a maximum amount of $10.00, for services furnished in a hospital emergency room if those services are not emergency medical services as defined in § 457.10. Under § 457.515(f), States must assure that enrollees will not be held liable for cost-sharing amounts beyond the co-payment amounts specified in the State plan for emergency services provided at a facility that does not participate in the enrollee's managed care network. Section 457.495(b) provides that in its State plan, a State must describe its methods for assuring the quality and appropriateness of care provided under the plan particularly with respect to access to covered services, including emergency services as defined at § 457.10.

• Participation in Treatment Decisions

This regulation gives enrollees in separate child health programs the right and responsibility to participate fully in treatment decisions. Under § 457.110, the State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants and enrollees and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. The State must also make available to applicants and enrollees information on the amount, duration and scope of benefits and names and locations of current participating providers, among other items. In addition, under § 457.985, States must guarantee that its contracts for coverage and services comply with the prohibition on interference with health care professionals' advice to enrollees, requirement that professionals provide information about treatment in an appropriate manner, the limitations on physician incentive plans, and the information disclosure requirements related to those physicians incentive plans referenced in that provision. We also require under § 457.110(b)(5) that the State have a mechanism in place to ensure that information on physician incentive plans, as required by § 457.985, is available to potential applicants, applicants and enrollees in a timely manner. We also provide under § 457.130 that the State plan must include an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR part 80, part 84, and part 91, and 28 CFR part 35.

• Civil Rights Assurances

In § 457.130, we require in the State plan an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR parts 80, 84, and 91, as well as 28 CFR part 35. These civil rights laws prohibit discrimination based on race, sex, ethnicity, national origin, religion, or disability.

• Confidentiality of Health Information

The regulations address this right in § 457.1110, which provides privacy protections to enrollees in separate child health programs. Under that section, the State must ensure that, for medical records and any other health and enrollment information maintained with respect to enrollees (in any form) that identifies particular enrollees; the State and its contractors must establish and implement certain procedures to ensure the protection and maintenance of this information.

• Review Process

Sections 457.1130(b) and 457.1150(b) provide that enrollees in separate child health programs must have an opportunity for an independent external review by the State or a contractor, other than the contractor responsible for the matter subject to external review, of a decision by the State or its contractor to delay, deny, reduce, suspend, or terminate health services, in whole or in part, including a determination about the type or level of services; or for failure to approve, furnish, or provide payment for health services in a timely manner. Section 457.1160(b) sets a time frame under which this process must occur, including an expedited time frame in the case where an enrollee's life or health or ability to attain, maintain or regain maximum function are in jeopardy.

2. Basis, Scope, and Applicability § 457.1100

This subpart interprets and implements section 2101(a) of the Act, which provides that the purpose of title XXI of the Act is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; section 2102(a)(7)(B) of the Act, which requires that the State plan

include a description of the methods used to assure access to covered services, including emergency services; section 2102(b)(2) of the Act, which requires that the State plan include a description of methods of establishing and continuing eligibility and enrollment; and section 2103, which outlines coverage requirements for a State that provides child health assistance through a separate child health program. This subpart sets forth minimum standards for applicant and enrollee protections that apply to separate child health programs.

3. Definitions and Use of Terms (Selected Provisions of Proposed § 457.902)

Below we will address the comments on the definitions in proposed § 457.902 and terms used in proposed § 457.985 that relate to the applicant and enrollee protections set forth in this new subpart K.

In proposed § 457.902, we defined contractor as ''any individual or entity that enters into a contract, or a subcontract to provide, arrange, or pay for services under title XXI of the Act. This definition includes, but is not limited to, managed care organizations, prepaid health plans, primary care case managers, and fee-for-service providers and insurers.'' As stated in the preamble to the proposed rule, we defined the term contractor in proposed § 457.902 because it is used most significantly in reference to accountability for ensuring program integrity. However, we also used the term in proposed § 457.985 relating to grievances and appeals. Because the term is now used in subparts I and K, we moved the definition of contractor to § 457.10. We retained the definition of contractor set forth in the proposed regulation. We defined the term ''grievance'' in proposed § 457.902 as ''a written communication, submitted by or on behalf of an enrollee in a child health program, expressing dissatisfaction with any aspect of a State, a managed care or fee-for-service entity, or a provider's operations, activities or behavior that pertains to—(1) The availability, delivery, or quality of health care services, including utilization review decisions that are adverse to the enrollee; (2) payment, treatment, or reimbursement of claims for health care services; or (3) issues unresolved through the complaint process established in accordance with § 457.985(e).'' In the preamble to the proposed rule, we indicated that we ''defined the term 'grievance' to provide some context into the section requiring States to have written procedures for grievances and appeals.'' We defined the term grievance to be consistent with the proposed Medicaid managed care regulations, and to give the States the opportunity to utilize the process that is already in place for the Medicaid program.

As noted earlier, we are now referring to the procedural protections afforded to applicants and enrollees in separate child health programs under this regulation as a ''review process.'' Because the term grievance is no longer used or needed in our provisions regarding the review process, we removed the definition from the regulation text.

Comment: One commenter noted that there is a definition of the term ''grievance,'' but no definition of the term ''appeal.'' Another commenter proposed that we delete the definition of grievance. Several commenters recommended that HCFA ensure that the terms ''grievance'' and ''appeal'' are employed consistently across all programs, including Medicare, Medicaid and SCHIP; these commenters expressed confusion about different uses of the terms ''grievance,'' ''appeal'' and ''complaint'' in these other programs. One commenter also questioned whether the reference to § 457.985(e) was intended to be to § 457.985(d). This commenter recommended that it would be clearer for HCFA to use the terminology used in the proposed Medicaid managed care regulations. Another commenter argued that federal requirements for resolving enrollee complaints and grievances will reduce plan participation because many plans will not be willing to have separate processes for SCHIP enrollees that exceed existing State statutory requirements.

Response: Consistent with our modified approach to requirements in this area, under which we give States flexibility in how they choose to handle many types of disputes, we removed the definition of ''grievance'' from the regulation text. We are now referring to the procedural protections afforded to enrollees in separate child health programs under this regulation as a ''review process.'' Therefore, we did not add a definition of ''appeal.'' We rectified the incorrect cross-reference noted by the commenter in removing the definition of grievance from the regulation text. We agree that, to the extent that we intend to impose Medicaid requirements, we should use the same terminology. In this regulation, however, we determined not to require States to adopt the Medicaid approach to review processes, but we did attempt to use consistent terminology as appropriate.

In order to assure the fair and efficient operation of SCHIP and to ensure that children eligible for coverage under separate child health programs have access to the health care services provided under title XXI, these final rules establish minimum consumer protection standards for applicants and enrollees in separate child health programs balancing a recognition that State law varies in this area with the need to assure certain protections to all children, regardless of where they live. If a contractor serving separate child health program enrollees is subject to State consumer protection law that is more prescriptive in the areas addressed by this regulation, then the contractor, in complying with State law, will comply with this Federal regulation as well.

Comment: Several commenters believed the term ''contractor'' as used in § 457.985(a) is too broad. One commenter said the definition appeared to include every fee-for-service physician that serves a participant in a separate child health program. According to this commenter, this rule makes such a physician's decision to provide Tylenol instead of an antibiotic subject to a grievance procedure. The commenter noted that this policy may discourage physician participation in the program and recommended that the statement exclude those providers to whom the enrollee is not ''locked in'' or whom the enrollee is not otherwise required to utilize. One commenter noted that inconsistency in the use of ''participating contractors'' in § 457.995(g)(1) and ''participating providers'' in § 457.985(a) resulted in confusion. Another commenter believed that the term ''participating providers'' as used in § 457.985(a) needed to be clarified because ''providers'' are generally defined as health care professionals, agencies or institutions. It was also not clear to this commenter why ''health providers'' would be included in this directive. If the term intended was contractors, in the view of this commenter, § 457.985(a) should be amended. If another meaning is intended, the commenter recommended that it be added to the definitions at § 457.902.

Response: We intended to include in the term ''contractor'' any individual or entity that would enter into a contract with a State to furnish child health assistance to targeted low-income children. As reflected in §§ 457.1130(b) and 457.1150(b), we believe enrollees must have an opportunity for an independent, external review of a

determination to delay, deny, reduce, suspend, or terminate health services, in whole or in part, including a determination about the type or level or services; or for failure to approve, furnish, or provide payment for health services in a timely manner. This right applies whether or not the actions mentioned were taken by a State directly or by a contractor. Because we believe that we accomplish this goal with the definition as proposed, we did not modify the definition of contractor. We agree that we created confusion by using ''participating contractors'' and removed § 457.995(g)(1) and its reference to ''participating contractors'' from the regulation text. We also agree that we created confusion by using the term ''participating providers'' and not defining it. Our intent was to ensure that applicants and enrollees receive written notice of decisions that they have the opportunity to challenge through a review process. In § 457.1180, we did not use the term ''participating providers,'' and clarified that a State must assure that applicants and enrollees receive timely written notice of any determinations subject to review under § 457.1130. This could be accomplished, for example, by requiring contracting managed care entities to provide notice either directly or through a provider serving as an agent of that entity.

4. Privacy Protections § 457.1110 (Proposed § 457.990)

We proposed that the State plan must assure that the program complies with the title XIX provisions as set forth under part 431, subpart F—Safeguarding Information on Applicants and Recipients. Moreover, we proposed that the State plan must assure the protection of information and data pertaining to enrollees by providing that all contracts will include guarantees that:

- Original medical records are released only in accordance with Federal or State law, or court orders or subpoenas;
- Information from or copies of medical records are released only to authorized individuals;
- Medical records and other information are accessed only by authorized individuals;
- Confidentiality and privacy of minors is protected in accordance with applicable Federal and State law;
- Enrollees have timely access to their records and to information that pertains to them; and
- Enrollee information is safeguarded in accordance with all Federal and State laws relating to confidentiality and disclosure of mental health records, medical records, and other information about the enrollees.

We proposed that State child health plans are subject to any Federal information disclosure safeguard requirements as well as requirements set forth by their State regarding information disclosure, including use of the Internet to transmit SCHIP data between and among the State and its providers. We also proposed that electronic transmission of data to HCFA must comply with HCFA's policies and requirements regarding privacy and confidentiality of data transmissions. Data transmissions between providers, health plans, and the State would be subject to these requirements. Finally, we proposed to provide that the State must assure that the program will be operated in compliance with all applicable State and Federal requirements to protect the confidentiality of information transmitted by electronic means, including the Internet.

Comment: One commenter strongly supported the inclusion of the Medicaid privacy protections for all SCHIP enrollees and the listed contract requirements regarding information protection and access for enrollees.

Response: We appreciate the commenter's support for the inclusion of the specific language relating to the Medicaid provisions, and we have retained this requirement in the final rule. As for the listed contract requirements regarding information protection and access for enrollees, we have modified slightly our requirements in the final rule. Specifically, we are requiring that for medical records and any other health information maintained with respect to enrollees that identifies particular enrollees, States and their contractors must abide by all applicable Federal and State law regarding confidentiality and disclosure; maintain records and information in a timely and accurate manner; specify the purpose for which information is used and disclosed; and except as provided by Federal or State law, ensure that enrollees may request and receive a copy of their records and request that information be supplemented or corrected. To minimize potential inconsistencies with other Federal regulations, we have removed the specific references to safeguarding electronic data transmissions, including the use of the Internet to transmit SCHIP data. Similarly, we have eliminated the language requiring safeguarding of information because subpart F of part 431 already includes such a requirement. We also clarify that original medical records and other identifiable information must be offered the same level of protection under this rule. These revisions should not be interpreted as a reduction in privacy protections. The protections addressed by the commenter will be afforded to SCHIP applicants and enrollees in separate child health programs, consistent with any other applicable law.

Comment: Two commenters supported the provision requiring that the State plan must provide that all contracts will include guarantees that protect the confidentiality and privacy of minors, subject to applicable Federal and State law. One commenter noted that both State and Federal law contain a variety of provisions that protect the confidentiality of minors. According to this commenter, minor consent statutes in every State accord minors the right to give their own consent for services and often provide confidentiality protection for minors as well. Another commenter believed that confidentiality is critical to ensure that adolescents seek health care services, particularly those related to reproductive health. Both adolescents and providers consistently identify concerns about confidentiality as a major obstacle to health care for adolescents. This commenter urged HCFA to encourage States to ensure that all information, including statements explaining benefits related to reproductive health services and family planning, is provided to enrollees in a confidential manner.

Response: We appreciate these commenters' support. The final rule requires States to abide by all applicable Federal and State laws regarding confidentiality and disclosure, including those laws addressing the confidentiality of information about minors and the privacy of minors, and privacy of individually identifiable health information.

Comment: One commenter recommended that HCFA explain in the preamble language how these privacy protections interact with the privacy standards proposed in October 1999 and the security standards proposed in August 1998. This commenter believed that it is extremely important that all of the protections are harmonized so that the legal interpretations of State and contractor obligations are not unnecessarily confusing. Other commenters noted that the SCHIP protections should be consistent with the rulemaking on Standards for Privacy of Individually Identifiable Health Information (**Federal Register**, November 3, 1999).

One commenter expressed general concern about what they viewed as the lack of consistency across the federal government and the States regarding privacy standards. The commenter noted that dual regulation increases compliance costs, which are ultimately passed on to enrollees and consumers. This commenter specifically suggested that § 457.990(b) be deleted and replaced with a requirement that the State health plan must assure the protection of information and data pertaining to enrollees by providing that all contracts contain identical privacy protections as required under current federal Medicaid contract requirements. If this change was not acceptable, the commenter had alternative suggestions. The commenter first noted that the term ''authorized individuals'' is not defined in § 457.990(b)(2) and § 457.990(b)(3) and suggested that clarification is necessary to ensure that this definition includes all parties needing access to enrollee information for treatment, administration, payment, health care operations and other appropriate purposes consistent with Medicaid standards. Second, this commenter suggested the need to clarify in § 457.990(b)(5) that enrollees' right to access information pertaining to them falls under the Federal Privacy Act of 1974.

Response: We agree with the need to harmonize the SCHIP privacy requirements and other Federal privacy law and policy, and as a result have made several changes to this section. In revising § 457.1110, we examined the proposed Medicaid Managed Care regulation (63 FR 52022), the proposed Medicare+Choice regulation (63 FR 34968), and the proposed requirements set forth under the authority of the Health Insurance Portability and Accountability Act (HIPAA). Additionally, we acknowledge the commenters' point that ''authorized individuals'' was not defined and have deleted it from the final regulations so as not to conflict with Federal or State law addressing permissible disclosures. We also elected not to specify particular Federal or State laws in the final regulation (in order to clarify that we intend to require that States follow all applicable Federal and State laws, including laws and regulations not yet finalized or developed).

Comment: One commenter recommended that HCFA review the American Academy of Pediatrics policy statement, ''Privacy Protection of Health Information: Patient Rights and Pediatrician Responsibilities'' (Pediatrics Vol. 104 No. 4, October 1999).

Response: We appreciate the suggestion that we review the Academy's report, and in our review found that it provided useful information regarding patient rights and pediatrician responsibilities from the Academy's perspective. We encourage providers and others to review the report for additional information on complying with aspects of Federal and State privacy law. For the purposes of this regulation, however, we attempted to harmonize the privacy requirements for separate child health programs with other applicable Federal law, and opted not to adopt additional measures.

Comment: One commenter expressed that § 457.995(f) is awkward in that it excludes confidentiality protections and access rights afforded by other laws, such as local or tribal laws, as well as industry practices that are more protective of confidentiality and provide greater access to health information. This commenter recommended removing the words ''only'' and ''federal and State law'' from § 457.995(f) so that it reads: ''States must ensure the confidentiality of a enrollee's health information and provide enrollees access to medical records in accordance with applicable law (§ 457.990).''

Response: As noted above, we removed § 457.995(f) from the regulation text. We considered this comment, however, with respect to proposed § 457.990(b)(1), (b)(4), and (b)(6). We did not intend the proposed privacy protections to preclude greater local or tribal protections or protections of enrollee access to information. However, depending upon the applicable Federal or State law, it is possible that local or tribal protections could be preempted if the Federal or State law in questions requires a preemption.

Comment: One State indicated that its separate child health program uses a premium assistance program under which it would not contract for health services and therefore would not have a mechanism to enforce the proposed privacy requirements. The State indicated that the mechanism available to impose these requirements is the State Insurance Code, and recommended it be recognized.

Response: States are required to ensure that enrollees in separate child health programs are covered by the minimum privacy protections defined under § 457.1110 of this regulation, regardless of what model is used to deliver services under a separate child health program funded with Federal SCHIP funds. If the premium assistance program is subject to State insurance law that requires the minimum privacy protections consistent with those set forth by this regulation, then the State will be in compliance with this requirement. If a group health plan participating in the State's premium assistance program does not comply with the minimum privacy requirements set forth in this regulation, then the State may not provide SCHIP coverage to separate child health program enrollees through that group health plan.

5. Review Processes §§ 457.1120–457.1190 (Proposed § 457.985)

In the proposed rule, we provided that the State and its participating providers must provide applicants and enrollees written notice of the right to file grievances and appeals in cases where the State or its contractors take action to: (1) deny, suspend or terminate eligibility; (2) reduce or deny services provided under the State's benefit package; (3) disenroll for failure to pay cost sharing. In addition, proposed sections §§ 457.365, 457.495, and 457.565, respectively, required that § 457.985 apply in these specific circumstances. In § 457.361(c), we proposed to require that the State must send each applicant a written notice of the decision on the application and if eligibility is denied or terminated, the specific reason or reasons for the action and an explanation of the right to request a hearing within a reasonable amount of time.

We further proposed in § 457.985(d) that the State must establish and maintain written procedures for addressing grievances and appeal requests, including processes for internal review by the contractor and external review by an independent entity or the State agency. We proposed that these procedures for grievances must comply with the State requirements for grievances and appeals that are currently in effect for health insurance issuers (as defined in section 2791(b) of the Public Health Service Act) within the State. We proposed that procedures must include a guarantee that the grievance and appeals requests will be resolved within a reasonable period of time.

We also proposed that States may elect to use the grievance procedures as described in part 431, subpart E regarding fair hearings for Medicaid applicants and recipients, and the Medicaid grievance and appeal procedures for Medicaid managed care entities, which were set forth in the Medicaid Managed Care proposed rule (63 FR 52022).

We further proposed to require that the States and their contractors must

have in place a meaningful process for reviewing and resolving complaints that are submitted outside of the grievance and appeals procedures as part of the quality assurance process.

In addition, we proposed at § 457.985(e) that the State must guarantee, in all contracts for coverage and services, enrollee access to information related to actions which could be subject to appeal in accordance with the ''Medicare+Choice'' regulation at § 422.206, which prohibits ''gag rules'' and protects enrollee-provider communications, and § 422.208 and § 422.210, which address limitations on physician incentive plans and requirements for information disclosure to enrollees related to those plans.

Following are responses to comments on proposed § 457.985.

Comment: One commenter suggested reorganizing § 457.985 into a more logical format to keep all of the grievance sections in one subpart, with cross-references as appropriate.

Response: We agree with this comment and made appropriate changes to the regulation text to consolidate provisions relating to the review process. In this final regulation, we moved proposed § 457.985(a),(b),(c), and (d) relating to review procedures from subpart I to subpart K, and further revised and clarified these sections.

We retained subparagraph (e) related to provider-enrollee communications and limits on physician incentives as the whole § 457.985 in subpart I. In addition, to improve clarity and to be responsive to comments, we revised that section.

Sections §§ 457.1120–457.1190 are the provisions of the final regulation that represent the reworking of proposed § 457.985. Subpart K now contains most of the provisions relating to the review process, and related provisions in other subparts were revised or deleted as appropriate, to be consistent with the provisions of subpart K.

Comment: Many commenters noted that the lack of minimum standards may cause lengthy time periods for completion of grievance and appeals processes, leaving many enrollees without needed benefits. The commenters believed that, despite the difficulties in establishing a grievance and appeals system that addresses the needs of States, participating contractors, Medicaid, and SCHIP, consistency between the Medicaid and SCHIP procedures is integral to ensuring ease of administration for providers and quality care for enrollees. The commenters noted that because enrollees may transfer between Medicaid and SCHIP at different times, consistency in the application of grievances and appeals processes would eliminate confusion. The commenters recommended that HCFA establish a set of minimum standards the States and participating providers must meet when providing services to enrollees.

Response: In finalizing this regulation, we attempted to strike a balance between State flexibility and enrollee protection consistent with the provisions and framework of title XXI. Rather than requiring Medicaid grievance and appeal requirements for separate child health programs, we adopted core elements for a review process under § 457.1140, and minimum standards for impartial review, under § 457.1150, that States with separate child health programs must meet. We also included, under § 457.1160, specific time frames for review of health services matters and a requirement that review of eligibility and enrollment matters be completed within a reasonable amount of time. We also required, in both cases, that States consider the need for expedited review in appropriate circumstances. We recognize that enrollees will often move between the two programs, and we encourage States to standardize the review processes to the extent possible and rely on Medicaid procedures when it is advisable to do so. In § 457.110, we also require that States notify potential applicants, applicants and enrollees of the procedural protections afforded to applicants and enrollees under the separate child health program. This information should help ease transition between Medicaid and separate child health programs, to the extent that a State chooses to implement different review systems.

Comment: Several commenters believed that grievance and appeal rights are inappropriate for title XXI. Likewise, one commenter believed that SCHIP is not an entitlement program and should not be subject to the grievance procedures required for entitlement programs. In the view of this commenter, HCFA has exceeded its statutory authority in applying the CBRR to the title XXI regulations. One commenter recommended deleting § 457.985 because, in their view, there is no basis for the development of Federal grievance or appeal processes in title XXI, and expressed that States should have the flexibility to develop and apply processes consistent with State law. Another commenter recommended also deleting § 457.365 because they believed we had exceeded our authority, and recommended that in the final rule a reference to all eligibility actions (denial, suspension, and termination) be incorporated in § 457.361(c).

Response: We acknowledge that a separate child health program may be quite different from a State's Medicaid program, and the final regulation does not require States to comply with the Medicaid requirements for grievance and appeal procedures. However, we believe that States operating separate child health programs under title XXI need to establish a review process and comply with minimum standards. While title XXI provides States with a great deal of flexibility, section 2101(a) of the Act provides that the ''purpose of the title is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner.'' As we asserted in the preamble to the proposed rule, review processes that meet certain minimum standards are essential components of State programs in order to assure that child health assistance is provided in an effective and efficient manner.

Moreover, section 2102(b)(2) requires that a State plan include a description of methods ''of establishing and continuing eligibility and enrollment.'' Procedures to address adverse determinations related to eligibility or enrollment are necessary for ensuring accurate assessments of initial and ongoing eligibility. Section 2102(a)(7)(B) requires a State in its State plan to describe methods used ''to assure access to covered services.'' This section supports our requiring minimal standards for a review process designed to ensure that eligible children have access to covered services, including an expedited review process when there is an immediate need for health services. Section 2103 also requires a specific scope of coverage, and provides the authority for the provisions of the final regulation that seek to assure that a meaningful review process is in place to enforce that access requirement. In the final regulation, eligibility actions and procedural protections related to such actions are described in §§ 457.1130(a), 457.1140, 457.1150(a), 457.1160(a), 457.1170, and 457.1180.

Comment: Several commenters believed States should be allowed to use existing appeal mechanisms for managed care. One commenter noted opposition to Federal requirements that would force the States to alter standard commercial plan contracts (for example, specific appeals criteria or procedures), and urged HCFA to allow States to develop appeals and grievance procedures that are consistent with State insurance regulations. Another

commenter noted that under New York law, Child Health Plus enrollees are granted broad grievance and utilization review rights, as well as external appeal rights for certain determinations. These rights are set forth in detail in the member handbook or contract, and whenever services under the program are denied as not medically necessary, individuals are advised of their appeal rights. This commenter supported allowing States to use existing procedures in lieu of ''Medicaid-style'' procedures. One commenter noted that such an approach is more efficient and that a separate grievance process would be problematic because the costs of it would be subject to the 10 percent administrative cap.

Response: As noted above, we do not require any particular type of review process. States have discretion under these rules to design their own review process and we fully expect that such procedures may vary from State to State while still operating consistent with the requirements adopted here. We recognize, however, that our review process requirements might necessitate changes in standard commercial contracts if such contracts are used in separate child health programs. However, we believe that these changes are likely to be minimal given the broad discretion left to States to establish their review procedures. The regulations provide a minimum level of protection to applicants and enrollees in separate child health programs. To the extent that the State health insurance law on reviews is more stringent than, but also complies with, these requirements and the State or its contractor is subject to that State health insurance law, these rules will not impose any new requirements on States or their contractors. We believe that title XXI ensures that enrollees enjoy some minimal procedural protections regardless of the State in which they reside.

Comment: Several commenters believed that HCFA should clarify that States with separate child health programs have flexibility in setting up appeals processes to determine what appeals are submitted to whom, and do not need to use the Medicaid procedures. For example, the commenters asked for clarification that, if a State uses the health plan or another appeals body for its review process, the State can have grievances sent directly to that entity.

Response: While the use of Medicaid fair hearing procedures for a separate child health program may be efficient for some States as it may eliminate the need for two parallel, and to some extent, duplicative processes, the use of Medicaid procedures is not required in a separate child health program. States may determine the structure of their review process as long as it complies with the minimum standards of this regulation. In order to alleviate any confusion created by the language of proposed § 457.985(c), which noted that States have the option to adopt the Medicaid procedures, we removed that language from the final regulation text.

Comment: One commenter believed that HCFA should clarify that States that have implemented Medicaid expansions must provide applicants and recipients all of the Medicaid protections.

Response: To clarify, States that implement Medicaid expansions must provide applicants and enrollees all of the Medicaid protections. Subpart K only applies to separate child health programs.

Comment: One commenter was concerned about the grievance procedures proposed in the Medicaid managed care regulations. The commenter was concerned about the meaning of the term ''complaint;'' obligations to submit the decision and case file to the State agency; issues arising from the State fair hearing process; the obligation of a managed care entity to issue a notice of intended action; administrative issues regarding how the organization handles complaints and grievances; and continuation of benefits obligations pending appeal.

Response: This commenter's concerns relate to the final regulation for Medicaid managed care, and are beyond the scope of this regulation. We direct interested parties to review the Medicaid managed care final rule, once published, for issues related to Medicaid managed care. Again, subpart K only applies and relates to separate child health programs.

Comment: One commenter requested that HCFA clarify whether a State that has existing laws relating to consumer protections is able to choose its Medicaid procedures instead. A different commenter suggested that the proposed regulations could be read to suggest that HCFA anticipates that States will use both the Medicaid procedures and procedures applicable to commercial health plans. However, this commenter noted that many States do not have the same grievance rules for Medicaid and for commercial health plans, so it may be impossible for managed care entities to meet both sets of requirements. This second commenter assumed that HCFA intended that the use of Medicaid procedures and procedures applicable to commercial health plans would be alternatives, and recommended that HCFA clarify this issue.

Response: As noted above, the use of Medicaid procedures may be efficient for States, but those procedures are not required. State laws applicable to commercial plans may or may not apply to a separate child health program, depending on the provisions of the State law. We expect that States that decide to adopt Medicaid procedures for the review process in their separate child health program will thereby be meeting State law requirements applicable to commercial health plans. However, this rule only establishes core elements and minimum standards for reviews; it does not require States to adopt Medicaid review procedures.

Comment: A few commenters proposed giving States three options to comply with requirements for grievance and appeals procedures: (1) processes that comply with the State grievance and appeal procedures currently in effect for health insurance issuers; (2) the Medicaid rules, systems and procedures; or (3) the Health Carrier External Review Model Act as developed by the National Association of Insurance Commissioners (NAIC).

Response: We appreciate the suggestion on possible models. However, rather than mandating a specific, detailed model that States must follow, we elected instead to establish core elements and minimum standards that reflect the most important aspects of these and other models of patient protection, but give States flexibility over the design of their review process. States can elect to use any model as long as that model addresses each of the core elements and meets or exceeds the minimum requirements set forth by this regulation.

Comment: One commenter supported internal review by the contractor and external review by an independent agency (or the State agency) for appeals related to eligibility, premiums and benefits. Another commenter questioned HCFA's requirement for external and internal review.

Response: We appreciate the support expressed by one of these commenters and acknowledge the diverging opinions on the value of internal and external reviews. In this final regulation, we address external review only, and only with regard to adverse health services matters. Under § 457.1130(b) of this final regulation, we require that a State ensure that an enrollee has the opportunity for external review of a decision by the State or its contractor to delay, deny, reduce, suspend, or terminate health services in whole or in

part, including a determination about the type or level of services; or for failure to approve, furnish, or provide payment for health services in a timely manner. Under § 457.1150(b) we require that States must provide enrollees with the opportunity for an independent, external review that is conducted either by the State or a contractor other than the contractor responsible for the matter subject to external review. States retain the flexibility to determine whether, how, and when to require internal review of these decisions and other kinds of decisions and actions. As for decisions relating to eligibility and disenrollment for failure to pay cost sharing, as described below, a review process that meets core elements outlined in § 457.1140, and applicable standards of §§ 457.1150–1180, will meet the standards set by these regulations. We note that under §§ 457.1150(a), we require that a review of an eligibility or enrollment matter as described in § 457.1130(a), must be conducted by a person or entity who has not been directly involved in the matter under review. This could be a State agency or an independent contractor employed by the State to assist with making eligibility determinations. The State may decide to use the same review process for reviews of eligibility and health services or different process at its discretion.

Comment: One commenter believed that the grievance and appeal system must be designed to provide enrollees with a single point of entry so that, regardless of the subject matter, enrollees file their grievances or appeals with a single State entity. The entity would then be responsible for assigning it to the appropriate reviewing authority.

Response: We recognize the importance of easy and clear access to the review process. In § 457.110(b)(6), we require States to make available to potential applicants, and to provide to applicants and enrollees information on the review process. We also require States to describe the core elements of their review process in their State plans, in part to assure that the public has input into the design of the review process. A single point of entry may be an efficient way to manage the process, particularly if the State decides that different entities will be responsible for reviewing health services and eligibility decisions. However, a single point of entry for the review process is not required by this final regulation.

Comment: One commenter expressed their view that the rules lack sufficient clarity and specificity to ensure that consumers will be accorded adequate due process protections in a State that does not adopt the Medicaid procedures. Accordingly, in this commenter's view, HCFA should outline the basic requirements that must be addressed by a State if it does not choose the Medicaid system. At a minimum, this commenter suggested that these requirements should specify: (1) the content of the written notice; (2) circumstances for continued benefits; (3) processing of grievances and fair hearings including exhaustion requirements; (4) the enrollees' rights and responsibilities during the grievance and fair hearing process; (5) standards for conduct of the hearing; and (6) time frames for expedited and final resolution of grievances and appeals.

Several commenters underscored the need for due process protections in title XXI because of the lack of entitlement to benefits under the program and recommended requiring the Medicaid procedures. One commenter suggested that families need full access to an impartial review process, timely and adequate notices, opportunities to review records and evidence and examine witnesses, the right to represent themselves or to bring a representative, the right to receive a decision promptly, and the right to prompt corrective action. According to this commenter, referencing State laws without applying specific standards will be inadequate to assure equitable treatment of children because some of the laws are loose and vague on matters such as the time period within which a grievance must be resolved, who must hear the appeal, and what notice must be provided.

Another commenter considered it inappropriate to allow States with separate child health programs to use less stringent appeal procedures than required under Medicaid. In the commenter's opinion, SCHIP benefits are targeted at low-income children who, like Medicaid eligibles and recipients, have limited resources. The commenter also noted that while SCHIP is not an entitlement, constitutional due process considerations may apply and require that recipients be afforded minimal protections. If this is the case, the commenter noted that HCFA's current proposed rule may not meet those standards.

Response: We agree with these commenters about the need to set forth minimum standards for procedural protection for States with separate child health programs and provide these protections in §§ 457.1120 through 457.1190 of the final regulation. We adopted many of the commenters' suggestions in these sections of the final regulation, consistent with basic principles of due process. We did not elect to issue requirements for exhaustion of an internal review process, opting instead to require external review of health services matters as described in § 457.1130 and setting maximum time frames for the completion of external review (and internal, if available) in § 457.1160(b). It is within each State's discretion whether and in what conditions internal review will be available. The requirement is that the external review be implemented within 90 days (taking into account the medical needs of the patient). If a State chooses to establish internal review, internal and external review must be completed within that time frame.

We also left to the State's discretion enrollee responsibilities during the review process, although the regulations do set forth basic enrollee rights in § 457.1140. Many of the other protections suggested by the commenters have been addressed throughout §§ 457.1120–457.1180. In these sections, we identify basic procedural protections that are common to most review procedures and that must be provided in the context of separate child health programs. However, in the interest of preserving State flexibility, we left many of the particular design elements related to implementing the protections to the State's discretion.

Comment: One commenter noted that clarification is needed with regard to which types of decisions are subject to which grievance and appeals processes.

Response: We acknowledge the need for clarification about the scope of the requirements relating to review processes and provide it in the final regulation at § 457.1130.

Comment: One commenter noted inequity in the fact that Medicaid expansion programs receive 75 percent FMAP for grievance and appeal activities while separate child health programs are required to pay for these activities within the 10 percent limit for administrative expenditures.

Response: As the commenter indicated, section 2105(c)(2) of the Act places a limit on administrative expenditures. The costs of a review process are subject to the enhanced matching rate under SCHIP and may or may not be considered administrative costs that fall under the 10 percent administrative cap, depending on the nature of the expenditure and the method by which it is paid. While there is no cap on administrative expenditures within Medicaid, such

expenditures consume far less than 10 percent of Medicaid spending. To the extent that a State relies on preexisting review mechanisms, such as those that may be operating under the State's insurance laws, the State's employee health plan or it's Medicaid program, further efficiencies may be realized.

Comment: Several commenters noted the need to include grievance or appeal protections for providers who contract with SCHIP managed care entities or with SCHIP programs on a fee-for-service basis. In the opinion of these commenters, such protections are necessary because many of these ''safety net'' providers cannot afford to have payments withheld, delayed or denied without an expedited process to challenge the actions of the managed care entity or SCHIP program. One State did not support the requirement that providers be given a notice of appeal.

Response: We agree that States need to adopt procedures to address these concerns, but did not include in the proposed regulation or incorporate in this final regulation a requirement that States adopt procedural protections for providers involved in disputes with a State or a contractor. Providers and their advocates may work at the State level to obtain such protections, which States have the flexibility to provide.

Comment: Several commenters recommended that the regulation require that bilingual workers and linguistically appropriate materials used in application assistance, including information relating to grievances and appeals, be made available to ensure that all applicants, including those with limited English proficiency and persons with disabilities (parents and guardians with disabilities) are given notice and understand their rights concerning eligibility. Commenters recommended that the preamble explain the title VI mandate requiring linguistic access to services and give examples of how States and contracted entities can comply. Two commenters asked that both the preamble and regulations make it clear that failure to provide linguistically and culturally appropriate notices and services is grounds for filing a grievance or appeal.

Response: We addressed these comments in subpart A along with other comments on § 457.110 and § 457.130.

Comment: One commenter on § 457.365 noted that the grievance and appeal provisions depend almost entirely on the ability of families to know about and comprehend the nature of the rights available. According to this commenter, organizations upon which families rely for information should be utilized in a family-friendly manner.

Response: In § 457.110 we set forth requirements regarding the availability of accurate, easily understood, linguistically appropriate information for potential applicants, applicants, and enrollees, including information about the review process. We also encourage organizations working with enrollees to provide appropriate assistance to enrollees' families in accessing and navigating the review processes in the State. Additionally, under § 457.1140(d)(1), we require that States provide applicants and enrollees with the opportunity to represent themselves or have representatives of their choosing in the review process.

- State plan requirement § 457.1120 (proposed § 457.985(b)).

Proposed § 457.985(b) required States to establish and maintain written procedures for addressing grievances and appeals. We received many comments to subpart A noting the need for more routinized public input into the development of the State plan. In order to ensure public input into the development of the grievance and appeal procedures and ensure that each State addresses the core elements as it designs its procedures, the final regulations require a State to describe its review process in its State plan, pursuant to § 457.1120. We believe that the combination of State flexibility, minimum Federal standards, and public input will produce systems that provide necessary and appropriate procedural protections without imposing a ''one size fits all'' approach.

- Matters Subject to Review § 457.1130 (proposed §§ 457.361(c), 457.365, 457.495, 457.565, 457.970(d), 457.985(a)).

Eligibility and Enrollment Matters

In § 457.361(c), we proposed to require that States provide an applicant whose eligibility is denied or an enrollee whose enrollment is terminated with an explanation of the right to request a hearing. In proposed § 457.985(a)(1) and (2), we proposed to require that States give applicants and enrollees written notice of their right to file grievances and appeals in cases where the State takes action to deny, suspend, or terminate eligibility, or to disenroll for failure to pay cost sharing. Section 457.365 of the proposed regulation provides that a State must provide enrollees in separate child health programs with an opportunity to file grievances and appeals for denial, suspension or termination of eligibility in accordance with § 457.985. Likewise, § 457.565 of the proposed regulation provided that a State must provide enrollees in separate child health programs with the right to file grievances and appeals as specified in § 457.985 for disenrollment from the program for failure to pay cost sharing. In § 457.970(d), we proposed that a State may terminate the eligibility of an applicant or enrollee for ''good cause'' other than failure to continue to meet the requirements for eligibility. We also provided that enrollees terminated for good cause must be given a notice of the termination decision that sets forth the reasons for termination and provides a reasonable opportunity to appeal the termination decision.

Comment: One commenter indicated that since title XXI is not an entitlement, and therefore children are not entitled to receive services, States should not be required to establish a grievance procedure for children terminated for good cause.

Response: As provided by § 457.1130(a), States must provide enrollees in a separate child health program with an opportunity for a review of a termination of eligibility. The opportunity for a review is an important component of a fair and efficient system that should apply regardless of whether a State believes that it terminated coverage for good cause. Indeed, in such a situation, the purpose of the review would be to allow the enrollee an opportunity to address whether there was good cause to terminate eligibility. Reviews serve an important purpose regardless of whether the coverage provided is considered to be an entitlement. In this final regulation, we removed proposed § 457.970(d) (concerning ''good cause'') because we found it unnecessary and the comments suggested it was potentially confusing. States have the flexibility to identify any number of reasons for terminating an enrollees's eligibility that are consistent with this regulation.

Comment: A few commenters believed that denials, suspensions, and terminations of eligibility should be reviewed under a different process than the internal and external review process set out in § 457.985(b). Several commenters also questioned the appropriateness of utilizing the envisioned grievance and appeals system for decisions regarding failure to pay cost sharing and noted that disenrollment for failure to pay cost sharing should be reviewed under a different process than that set out in § 457.985. One commenter suggested that HCFA require States to use their Medicaid grievance and fair hearing process for eligibility and disenrollment determinations rather than deferring to

internal appeals or State-specific insurance practices.

Response: We agree with the comment that internal and external review consistent with State insurance law may not be the appropriate form of review for eligibility and enrollment matters, but we leave this matter to State discretion, as long as the minimum review requirements are met. A State may use the same process for reviewing eligibility and enrollment decisions as it uses to review health services decisions, or it may use different processes as long as the requirements pertaining to each type of review are met.

Comment: One commenter suggested that HCFA permit applicants and enrollees to file grievances and appeals on the grounds that eligibility determinations were limited or delayed.

Response: We agree that an enrollee should be given the opportunity for a review to address the failure to make a timely eligibility determination. Section § 457.1130(a) requires a review to address such a situation. As for the case of a limitation of eligibility, we believe that denials, reduction, or terminations of eligibility encompass and therefore require an opportunity for review of a decision to limit eligibility.

Comment: One commenter believed that HCFA should modify its regulations to allow reasonable exceptions to grievance requirements, such as when disenrollment or suspension of services results from a State exceeding its allotment.

Response: Under § 457.1130(c), we provide an exception and do not require a State to provide an opportunity for review of an adverse eligibility, enrollment, or health services matter if the sole basis for the decision is a provision in the State plan or in Federal or State law that requires an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances. If a State stopped enrolling new applicants because it had spent all of its allotted funds, this would likely be a situation where applicants would not need to be granted a review of the denial of their application. Whether a review would be required would depend on whether the denial was automatic and applied broadly. For example, if a State with limited funds amended its approved State plan to enroll only new applicants with special health care needs, an opportunity for review would be required to provide denied applicants an opportunity to establish that they met the State's enrollment criteria. However, if a State exceeds its allotment and no longer wishes to operate its State plan as approved, the State could either keep the plan in place and, pursuant to the State plan, suspend operation of the program until the beginning of the next Federal fiscal year when additional funding becomes available, or request withdrawal of its State plan by submitting a State plan amendment to HCFA as described in §§ 457.60 and 457.170. Under each of these scenarios, the State would no longer be approving any new applications and as such, reviews of application denials or suspensions would not be subject to the review requirements.

Health Services Matters

In § 457.985(a)(3), we proposed to require the State to provide the right to file grievances and appeals in cases where the State or its contractors take action to ''reduce or deny services provided for in the benefit package.'' In addition, proposed § 457.495 required States to provide enrollees in a separate child health program the right to file grievances or appeals for reduction or denial of services as specified in § 457.985.

We note that the range of health services-related matters required to be subject to review under the final rule is more narrow than the range of matters included within the definition of grievance in the proposed rule.

Comment: Several commenters agreed with the inclusion of § 457.985 in the proposed rule but encouraged modification of the provision to include the right to file a grievance or appeal for the *termination* of services as well as for reduction or denial of services *in whole or in part.*

Response: We agree with this comment, and § 457.1130(b)(1) of the final rule reflects that States must ensure that an enrollee has an opportunity for external review of matters related to delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of services.

Comment: A commenter suggested that HCFA should permit applicants and enrollees to file grievances and appeals on the grounds that requests for covered services were limited or delayed.

Response: We agree with the comment, and in § 457.1130(b)(2), we require States to ensure an enrollee has an opportunity for external review of a failure to approve, furnish, or provide payment for health services in a timely manner.

Comment: One commenter noted that the system of review to an independent body should resemble the Medicaid system to the extent possible, in order to ease the burden on providers and to provide continuity for families who move between programs.

Response: We recognize the importance of easing the burden on providers and on families who move between a separate child health program and Medicaid. However, we decided not to require that the external review for separate child health programs mirror the external review process required under Medicaid and to take a more flexible approach consistent with title XXI. We note that some States have chosen to adopt the Medicaid model for reviews in order to have a consistent system of review for their child health programs.

Comment: One commenter indicated that States should provide a timely appeals process that includes direct discussion between the reviewing panel, the patient's physician and the relevant specialists and, if appropriate, an external review by an independent panel of pediatricians experienced in the treatment of the patient's illness.

Response: We agree with the need for a timely process. Under § 457.1140(b), review standards must be timely in accordance with the time frames set forth under § 457.1160. However, under this final regulation, we have not prescribed the type of communication that must be allowed between the enrollee's physician and any review panel. The State has the leeway to require consultation with the enrollee's provider and/or with independent physicians, within the framework of the minimum standards established by these rules.

Comment: One commenter believed that § 457.985(d) should be deleted because the term ''complaint'' is not defined and it is not clear what type of problem constitutes a complaint that would end up outside the grievance and appeals processes. The commenter noted that it is also unclear who would be responsible for making such a determination, and what would happen should the plan decide that a consumer's grievance is really only a ''complaint,'' or vice versa. In this commenter's view, the regulation should not sanction the development or utilization of ''complaint'' systems that fall outside of the grievance and appeals process.

Response: We have deleted proposed § 457.985(d) from the regulation text because we agree that its provisions were unclear. Under the final regulation, we decided only to require